SAFETY SUMMARY REPORT

Prepared for the Safety Monitoring Committee for
DMID Protocol 20-0003:
Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults

02 JUNE 2020

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Notes on this Report

The following notes are provided for clarification of the data included in this safety report:

- Study accrual and vaccinations remain ongoing at the time of this report.
- Data entry, querying, and monitoring are in progress at the time of the report. The data are neither clean nor complete.
- At the time of the data cutoff for this report, 25 May 2020, there were no SAEs reported. If any additional SAEs are reported between the time of this report preparation and the SMC meeting, the details of those events will be provided to the SMC separately.
- Appendices are presented in a separate file named 20-0003_SMC_Report_02JUN2020_appendices.pdf.
SAFETY SUMMARY REPORT
DMID Protocol 20-0003

Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults

1. SUMMARY

DMID Protocol 20-0003 is examining the safety and immunogenicity of a 2019-nCoV vaccine (mRNA-1273 manufactured by ModernaTX, Inc.), for the prevention of 2019-nCoV (SARS-CoV-2) infection. Males and non-pregnant females, 18-55, 56-70, and ≥ 71 years old, inclusive, who are in good health and meet all eligibility criteria will receive 2 doses (Days 1 and 29) of mRNA-1273 at 25 mcg, 100 mcg or 250 mcg.

As of the data cutoff date of May 25, 2020, a total of 85 subjects had been enrolled into this study, and vaccination records had been submitted for 85 of those subjects for the first dose of vaccine; 61 of these 85 subjects had received the second dose of vaccine. The safety data presented in this report focus on both solicited and unsolicited events experienced by subjects following vaccination and entered in the study database as of the data cutoff date for this report.

2. PURPOSE OF THE REPORT

This report provides an interim update on the study of 85 subjects enrolled and vaccinated as of May 25, 2020.

3. REVIEW OF THE STUDY DESIGN

This is a Phase I, dose-ranging, open-label, sequential study comparing the immunogenicity and safety of 2019-nCoV mRNA-1273 vaccine in subjects receiving 2 doses (Days 1 and 29) at 25 mcg, 100 mcg and 250 mcg.

Potential subjects will be screened by medical history, physical exam, vital signs, and clinical laboratory tests including white blood cells (WBC), hemoglobin (Hgb), platelet count, total bilirubin, alanine aminotransferase (ALT), Aspartate aminotransferase (AST), serum lipase, Alkaline Phosphatase (ALP), Prothrombin time (PT), Partial thromboplastin time (PTT), and creatinine (Cr). Height and weight will be obtained to calculate BMI. Urine will be collected for drug screening. Potential female subjects of childbearing potential will have a serum pregnancy test. In addition, potential subjects will be screened for HIV 1 and 2 antibody, Hepatitis C antibody, and Hepatitis B surface antigen prior to study product administration.

For this report eighty-five subjects were enrolled into one of seven cohorts as shown below. Subjects will receive an IM injection of mRNA-1273 on Days 1 and 29 in the deltoid and will be followed through 1-year post 2nd vaccination (Day 394). The second dose of vaccine (0.5 mL) will
be administered preferably in the same arm used for the first dose. Follow up visits will occur 1, 2, and 4 weeks after each vaccination (Days 8, 15, 29, 36, 43, and 57), as well as 3 months, 6 months and 12 months after 2nd vaccination (Days 119, 209, and 394). Safety endpoints will be assessed at these visits as well as blood drawn for immunogenicity assays. Additional safety and reactogenicity data will be solicited via phone calls to subjects 1 and 2 days post each vaccination (Days 2, 3, 30, and 31).

To determine early safety signals for this Phase 1 study, vaccination will proceed in a staged fashion. Sentinel subject dosing will begin with four subjects in cohort 1 (25 mcg). The four sentinel subjects for cohort 2 (100 mcg) will be enrolled no earlier than one day after enrollment of the last of the four sentinel subjects in cohort 1. If no halting rules are met for these eight sentinel subjects after Day 5, then full enrollment will proceed first with the remaining subjects in cohort 1, followed by the remaining subjects in cohort 2, without interruption. If no halting rules have been met after all subjects in cohort 2 have completed Day 8, dosing of four sentinel subjects will begin in cohort 3. If no halting rules are met after Day 5, then full enrollment of cohort 3 will proceed.

If no halting rules have been met after all subjects in cohorts 1 and 2 have completed Day 8, dosing will begin for cohorts 4 (25 mcg; 56-70 years of age) and 5 (100 mcg; 56-70 years of age). If no halting rules have been met after all subjects in cohorts 4 and 5 have completed Day 8, dosing will begin for cohorts 7 (25 mcg; ≥71 years of age) and 8 (100 mcg; ≥71 years of age).

### Vaccination Arms

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Sample Size</th>
<th>Age</th>
<th>First and Second Dose</th>
</tr>
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<tbody>
<tr>
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<td>18-55</td>
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<td>18-55</td>
<td>100 mcg mRNA-1273</td>
</tr>
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<td>3</td>
<td>15</td>
<td>18-55</td>
<td>250 mcg mRNA-1273</td>
</tr>
<tr>
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<td>10</td>
<td>56-70</td>
<td>25 mcg mRNA-1273</td>
</tr>
<tr>
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<td>10</td>
<td>56-70</td>
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</tr>
<tr>
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<td>10</td>
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<td>25 mcg mRNA-1273</td>
</tr>
<tr>
<td>8</td>
<td>10</td>
<td>≥71</td>
<td>100 mcg mRNA-1273</td>
</tr>
</tbody>
</table>

**Note:** Cohorts 6 and 9 have not been enrolled as of the time of this report and therefore are not included.

On vaccination days, all females of childbearing potential will have a urine pregnancy test done. All subjects will have vital signs measured and a physical examination pre-vaccination. Blood will be collected pre-vaccination for immunogenicity testing. On vaccination days, clinical safety laboratory tests will be collected pre-vaccination. Vaccine will then be administered by intramuscular injection.
Subjects will be observed for at least 60 minutes after the injection is given. Reactogenicity will be measured by the occurrence of solicited injection site and systemic AEs. Subjects will maintain a memory aid through 7 days post each vaccination recording temperature, solicited local and systemic symptoms. Unsolicited non-serious AEs will be collected from the time of first study vaccination through approximately 28 days after the last vaccination. From Day 57 through completion of study participation, only SAEs, MAAEs, and NOCMCs will be recorded as AEs in the study database. Clinical safety labs will be collected on Days 1, 8, 29 and 36.

Evaluation of immunogenicity will include quantitation of antibodies to the 2019-nCoV S protein at multiple timepoints following each study vaccination as measured by ELISA, pseudovirus and live virus neutralization assays. In addition, exploratory studies to characterize T and B cell responses as well as determination of major antigenic sites and amino acid residues on the 2019-nCoV S protein recognized by B cell clones are planned. Venous blood will also be collected at multiple time points following study vaccination for the secondary research use of serum, plasma and peripheral blood mononuclear cells (PBMCs).

4. METHODS FOR SAFETY ASSESSMENTS

A summary of the procedures for vaccination and follow-up of the study cohort is provided in the protocol.

Brief descriptions of the collection and protocol definitions of adverse events, serious adverse events, and the grading scales for solicited events, clinical laboratory results, and vital signs are excerpted from the protocol (Version 3.0, 30 March 2020) and included in Appendix A.

5. REVIEW OF THE SAFETY DATA

5.1 Overview

The safety data presented in this report focus on both solicited and unsolicited events experienced following product administration. Adverse events are reported to the staff at Kaiser Permanente Washington Health Research Institute, Emory Children’s Center and Hope Clinic of the Emory Vaccine Center.

The report includes the available safety data from subjects who received study product with data entered into the study database as of the data cutoff date of May 25, 2020. The monitoring of the data collected to date remains ongoing. The data are not considered clean.

5.2 Study Status

Enrollment was initiated on 16 March 2020. As of the data cutoff date for this report, 85 subjects have been enrolled, 85 subjects had received the first dose of vaccine and 61 subjects had received 2 doses of vaccine. 193 potential subjects were screened to accrue this number, for an overall
screening failure rate of 56%. The most common reasons for screening failure were Screening laboratory evaluations are not within acceptable normal ranges (44%), Systolic BP is not within the allowable range of 85 to 150 mmHg, inclusive (9%), and Has any medical disease or condition that precludes study participation (6%).

Tables 2A-2F present demographic characteristics (sex, ethnicity, race, and age) of the subjects enrolled in the study who have received study product.

Of the 45 subjects enrolled into the 18-55 years of age cohorts, 38 (84%) reported their ethnicity as not Hispanic or Latino; 40 (89%) subjects reported their race as White, 2 (4%) subjects reported their race as Black, 1 (4%) subject reported their race as American Indian or Alaska Native, and 1 (4%) subject reported their race as Unknown. The mean age in the 18-55 years of age cohorts is 33.0 years and the range is 18 to 53 years; the mean BMI is 25.34 kg/m^2 and the range is 20.4 to 32.6 kg/m^2.

Of the 20 subjects enrolled into the 56-70 years of age cohorts, 20 (100%) reported their ethnicity as not Hispanic or Latino; 20 (100%) subjects reported their race as White. The mean age in the 56-70 years of age cohorts is 64.8 years and the range is 56 to 70 years; the mean BMI is 24.56 kg/m^2 and the range is 20.8 to 29.5 kg/m^2.

Of the 20 subjects enrolled into the ≥71 years of age cohorts, 19 (95%) reported their ethnicity as not Hispanic or Latino; 19 (95%) subjects reported their race as White, and 1 (5%) subject reported their race as Asian. The mean age in the ≥71 years of age cohorts is 72.7 years and the range is 71 to 75 years; the mean BMI is 25.39 kg/m^2 and the range is 20.1 to 28.7 kg/m^2.

Table 2G shows the percentage of subjects in each vaccination group that have completed the study milestones and Tables 2H-2J display subject disposition. A total of 193 subjects were screened, and 85 were enrolled and 85 received treatment. 85/85 (100%) subjects have completed the Day 8 visit and 77/85 (91%) have completed the Day 15 visit. As of the data cutoff, four subjects discontinued treatment on the study; three of those subjects discontinued due to an AE (Hives on Lower Extremities, Sore Throat, and Maculopapular Rash), the other subject discontinued treatment due to COVID-19 exposure.

For a listing of subjects who have discontinued treatment and subjects who have terminated early from the study, see Table 2K.

5.3 Halting Rules Surveillance

The status of the study Halting Rules is summarized in Table 1.
TABLE 1: Study Halting Rules

<table>
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<tr>
<th>Halting Rule #</th>
<th>Halting Rule Description</th>
<th>Number of Subjects n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Any subject experiences an SAE after administration of the vaccine that is considered related to vaccine.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2</td>
<td>Any subject experiences laryngospasm, bronchospasm or anaphylaxis within 24 hours after administration of vaccine that is considered related to vaccine.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3</td>
<td>Any subject experiences ulceration, abscess or necrosis at the injection site that is considered related to vaccine administration.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4</td>
<td>Two (2) or more subjects experience an allergic reaction such as generalized urticaria (defined as occurring at three or more body parts) within 72 hours after administration of vaccine that is considered related to vaccine.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>5</td>
<td>Three (3) or more subjects experience a Grade 3 AE (systemic and/or clinical laboratory abnormality), in the same Preferred Terms based on the Medical Dictionary for Regulatory Activities (MedDRA) coding, that lasted at least 48 hours after administration of the vaccine and is considered related to the vaccine. Clinical laboratory abnormalities are not subject to the time window.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>6</td>
<td>Additionally, any AE for which the investigator checks the box for &quot;In the opinion of the site investigator, this event should be evaluated for possible contribution toward the halting criteria for the group, cohort, or study&quot; will trigger an automatic email from the EDC, even if it does not meet any of the requirements in the table above.</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

**NOTE:** No halting criteria have been met as of May 25, 2020.

Details of reported serious adverse events, if any, are included in **Table 3A**.

### 5.4 Adverse Events

Details of reported serious adverse events, medically attended adverse events (MAAEs), and new onset chronic medical conditions, if any, are included in **Table 3A and 3B**. Three MAAEs have been reported in 2 subjects as of data cutoff. One subject (50%) in the 56-70 years of age cohorts that received the 100 mcg dose reported 2 MAAEs after receiving one dose of the investigational product, with one in the Infections and infestations MedDRA® System Organ Class (SOC), and one in the Skin and subcutaneous tissue disorders SOC. One subject (50%) in the 18-55 years of age cohorts that received the 250 mcg dose reported one MAAE after receiving one dose of the investigational product in the Respiratory, thoracic and mediastinal disorders SOC. All MAAEs were assessed to be not related to the study product.

**Tables 4A-4I** summarize all unsolicited adverse events reported for subjects as of the data cutoff date. **Tables 4A, 4B, and 4C** classify each event in terms of MedDRA® System Organ Class (SOC), severity, and relationship to vaccination. **Tables 4D-4I** classify the events by MedDRA® SOC, Preferred Term (PT), relationship to vaccination, and severity. **Figure 1A-C** is a graphical...
representation of the number and severity of all unsolicited adverse events by System Organ Class. Appendix B is a listing of all unsolicited events grouped by cohort and dose number.

At the time of data cutoff, in the 18-55 years of age cohorts, 32 subjects (71%) had reported 82 unsolicited adverse events. Sixty four (78%) of the events were determined to be mild (Grade 1) severity, sixteen (20%), were determined to be moderate (Grade 2) severity, and two (2%) were determined to be severe (Grade 3) severity; 32 (39%) of the events were determined to be related to study product, and 50 (61%) were determined to be not related to study product. Two events were reported within the Cardiac Disorders SOC, both reported as mild Bradycardia. Two events were reported within the Eye Disorder SOC, including one incidence of mild eye irritation and one incidence of mild scintillating scotoma. Ten events were reported within the Gastrointestinal SOC, including 1 incidence of mild abdominal discomfort, 1 incidence of moderate abdominal pain, 1 incidence of mild abdominal pain upper, 1 incidence of mild faeces discoloured, 1 incidence of mild flatulence, 1 incidence of mild lip disorder, and 4 incidences of vomiting (2 mild and 2 moderate). Eighteen events were reported within the General Disorders and Administration site SOC, including 1 incidence of mild abdominal discomfort, 1 incidence of moderate abdominal pain, 1 incidence of mild abdominal pain upper, 1 incidence of mild faeces discoloured, 1 incidence of mild flatulence, 1 incidence of mild lip disorder, and 4 incidences of vomiting (2 mild and 2 moderate). Eighteen events were reported within the General Disorders and Administration site SOC, including 1 incidence of mild abdominal discomfort, 1 incidence of moderate abdominal pain, 1 incidence of mild abdominal pain upper, 1 incidence of mild faeces discoloured, 1 incidence of mild flatulence, 1 incidence of mild lip disorder, and 4 incidences of vomiting (2 mild and 2 moderate).
hypertension, 1 incidence of mild hypotension, 1 incidence of mild systolic hypertension and 1 incidence of mild vasodilation.

At the time of data cutoff, in the 56-70 years of age cohorts, 14 subjects (70%) had reported 16 unsolicited adverse events. Ten (63%) of the events were determined to be mild (Grade 1) severity, five (31%), were determined to be moderate (Grade 2) severity, and one (6%) was determined to be severe (Grade 3) severity; 3 (19%) of the events were determined to be related to study product, and 13 (81%) were determined to be not related to study product. One event was reported within the ear and labyrinth disorder SOC, one incidence of mild vertigo, two events were reported within the General Disorders and Administration site SOC, including 1 incidence of mild injection site bruising and, 1 incidence of mild vaccination site bruising. One event was reported within the Infections and infestations SOC, including 1 incidence of mild paronychia. One event was reported within the Injury, Poisoning and Procedural Complications SOC, including 1 incidences of mild exposure via inhalation. Two events were reported in the Metabolism and nutrition disorders, including 1 incidence of moderate decreased appetite, and 1 severe hypoglycaemia. Two events were reported within the Nervous System Disorders SOC, including 1 incidence of mild headache and 1 incidence of mild sciatica. One event was reported in the Psychiatric disorders SOC, including 1 incidence of mild insomnia. Three events were reported within the Respiratory, Thoracic and Mediastinal Disorder SOC, including 1 incidence of moderate nasal congestion and 2 incidences of mild oropharyngeal pain. One event was reported within the Skin and Subcutaneous tissue disorder SOC, including 1 incidence of moderate rash maculo-papular. Two events were reported within the Vascular Disorders SOC, including 1 incidence of mild diastolic hypertension, and 1 incidence of mild systolic hypertension.

At the time of data cutoff, in the 71 years of age and over cohorts, 10 subjects (50%) had reported 16 unsolicited adverse events. 15 (94%) of the events were determined to be mild (Grade 1) severity and one (6%) was determined to be moderate (Grade 2) severity; 5 (31%) of the events were determined to be related to study product, and 11 (69%) were determined to be not related to study product. Five events were reported within the General Disorders and Administration site SOC, including 1 incidence of mild increased energy, 2 incidences of mild injection site bruising and, 2 incidences of mild vessel puncture site bruise. Four events were reported within the Injury, Poisoning and Procedural Complications SOC, including 1 incidences of mild arthropod bite, 2 incidences of mild skin abrasion and 1 incidence of mild sunburn. Two events were reported in the Musculoskeletal and connective tissue disorders, including 1 incidence of mild joint swelling, and 1 incidence of moderate musculoskeletal chest pain. One event was reported within the Nervous System Disorders SOC, including 1 incidence of mild dizziness. One event was reported in the Psychiatric disorders SOC, including 1 incidence of mild anxiety. Three events were reported within the Skin and Subcutaneous tissue disorder SOC, including 1 incidence of mild dermatitis, 1 incidence of mild night sweat and 1 incidence of pruritus.
Refer to Appendix B for a detailed listing of moderate and severe non-serious, unsolicited, adverse events.

5.5 Solicited Events and Symptoms

Solicited events data, collected in-clinic pre-vaccination, post-vaccination and via memory aid through 7 days after vaccination, are summarized by symptom in Figure 2A(i, ii)-2C(i, ii) and Table 5A(i, ii, iii)-5C(i, ii, iii), which report the maximum severity experienced by each subject over the 7-day post-vaccination reporting period, separated by Dose 1 and Dose 2.

Tables 6A(i, ii, iii)-6J(i) and 7A(i, ii, iii)-7J(i) summarize the number of subjects who experienced a mild, moderate, or severe event for each symptom and across all symptoms for each day post-vaccination, separated by Dose 1 and Dose 2. Tables 6A-6C summarize the solicited systemic symptoms, and Tables 7A-7C summarize the solicited local symptoms. The row entitled "Not Reported" represents values that were missing on forms submitted into the database. This row does not take into account missing values due to forms not yet being submitted.

Figures 3A(i, ii, iii) and 4A(i, ii, iii) summarize the solicited event data across all vaccination groups and display the maximum severity experienced by each subject post-vaccination and on each day for all systemic and all local symptoms, respectively.

The graphical summaries of solicited events included in this report convey the number of subjects who experienced a maximum severity of mild (yellow), moderate (orange), or severe (red) during the post-vaccination period.

Twenty-five (55.6%) subjects in the 18-55 age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day, 14 (31.1%) subjects experienced a maximum moderate/grade 2 solicited local event for at least one day, and 2 (4.4%) subjects experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 7 (15.6%) subjects reported experiencing a maximum of mild erythema/redness. Six (13.3%) subjects reported experiencing a maximum of mild induration/swelling with 1 (2.2%) subject experiencing a maximum of moderate induration/swelling. Twenty-eight (62.2%) subjects reported experiencing a maximum of mild injection site pain with 13 (28.9%) experiencing a maximum of moderate injection site pain.

Nine (20%) subjects in the 18-55 age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day, 14 (57.8%) subjects experienced a maximum moderate/grade 2 solicited systemic event for at least one day, and 3 (6.7%) subjects experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 5 (11.1%) subjects reported experiencing a maximum of mild arthralgia, and 7 (15.6%) subjects reporting a maximum of moderate arthralgia. 11 (24.4%) subjects reported experiencing a maximum of mild fatigue, 16 (35.6%) subjects reported experiencing a maximum of moderate fatigue, and 2 (4.4%) subjects reported experiencing a maximum of severe fatigue.
experiencing a maximum of severe fatigue. Ten (22.2%) subjects reported experiencing a maximum of mild fever, 3 (6.7%) subjects reported experiencing a maximum of moderate fever, and 1 (2.2%), subject experienced a maximum of severe fever. Thirteen (28.9%) subjects reported experiencing a maximum of mild feverishness, 9 (20%) subjects reported experiencing a maximum of moderate feverishness, and 3 (6.7%), subjects experienced a maximum of severe feverishness. Eighteen, (40%) subjects reported experiencing a maximum of mild headache, 10 (22.2%) subjects reported experiencing a maximum of moderate headache, and 1 (2.2%), subject experienced a maximum of severe headache. Ten (22.2%) subjects reported experiencing a maximum of mild myalgia, 14 (31.1%) subjects reported experiencing a maximum of moderate myalgia, and 1 (2.2%), subject experienced a maximum of severe myalgia. Seven (15.6%) subjects reported experiencing a maximum of mild nausea, 4 (8.9%) subjects reported experiencing a maximum of moderate nausea, and 1 (2.2%), subject experienced a maximum of severe nausea.

Fifteen (75%) subjects in the 56-70 age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day, and 2 (10%) subjects experienced a maximum moderate/grade 2 solicited local event for at least one day. Post any vaccination, 4 (20%) subjects reported experiencing a maximum of mild erythema/redness, 6 (30%) subjects reported experiencing a maximum of mild induration/swelling. Fourteen (70%) subjects reported experiencing a maximum of mild injection site pain, and 1 (5%) subject experienced a maximum of moderate injection site pain.

Eight (40%) subjects in the 56-70 age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day, 6 (30%) subjects experienced a maximum moderate/grade 2 solicited systemic event for at least one day, and 1 (5%) subject experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 2 (10%) subjects reported experiencing a maximum of mild arthralgia, and 4 (20%) subjects reporting a maximum of moderate arthralgia. 5 (25%) subjects reported experiencing a maximum of mild fatigue, and 5 (25%) subjects reported experiencing a maximum of moderate fatigue. One (5%) subject reported experiencing a maximum of mild fever. Two (10%) subjects reported experiencing a maximum of mild feverishness, and 3 (15%) subjects reported experiencing a maximum of moderate feverishness. Six (30%) subjects reported experiencing a maximum of mild headache, and 2 (10%) subjects reported experiencing a maximum of moderate headache. Seven (35%) subjects reported experiencing a maximum of mild myalgia, and 3 (15%) subjects reported experiencing a maximum of moderate myalgia. Two (10%) subjects reported experiencing a maximum of mild nausea, and 1 (5%) subject reported experiencing a maximum of moderate nausea.

Fourteen (70%) subjects in the 71+ age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day. Post dose 1, 1 (5%) subject reported experiencing a maximum of mild erythema/redness, and 14 (70%) subjects reported experiencing a maximum of mild injection site pain.
Eight (40%) subjects in the 71+ age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day. Post dose 1, 1 (5%) subject reported experiencing a maximum of mild arthralgia. 5 (25%) subjects reported experiencing a maximum of mild fatigue. 1 (5%) subject reported experiencing a maximum of mild feverishness. Three (15%) subjects reported experiencing a maximum of mild headache. Five (25%) subjects reported experiencing a maximum of mild myalgia.

A listing of systemic and local solicited events is provided in Appendix C1-C2. The listing is limited to subjects who experienced a symptom of moderate or greater severity on at least one occasion.

Appendix D is a listing of all severe systemic solicited events contributing to halting criteria along with their attributions.

5.6 Clinical Laboratory Results and Vital Signs

Tables 8A-8L summarize the results of the scheduled hematology and chemistry clinical laboratory parameters conducted at the protocol specified visits. Figure 5A-C displays abnormal results by laboratory parameter and severity and takes into account all values reported after vaccination (scheduled and supplemental).

Appendix E includes listings of clinical laboratory results for subjects who experience abnormal hematology and chemistry results at any time post-vaccination.

Thirty-six (80%) subjects in the 18-55 age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination, and 3 (7%) subjects experienced a maximum moderate/grade 2 abnormal hematology result post-vaccination. Thirty five (78%) subjects experienced a maximum mild abnormal hemoglobin result and 3 (7%) of subjects experienced a maximum moderate abnormal hemoglobin result. Seven (16%) subjects experienced mild leukopenia.

Seventeen (85%) subjects in the 56-70 age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination, 2 (10%) subjects experienced a maximum moderate/grade 2 abnormal hematology result post-vaccination, and 1 (5%) subject experienced a maximum severe/grade 3 abnormal hematology result post-vaccination. Seventeen (85%) subjects in the 56-70 age group experienced a maximum mild abnormal hemoglobin result, 2 (10%) subjects experienced a maximum moderate abnormal hemoglobin result, and 1 (5%) subject experienced a maximum severe abnormal hemoglobin result. One (5%) subject experienced a maximum mild leukopenia result.

Nineteen (95%) subjects in the 71+ age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination. Seventeen (85%) subjects experienced a maximum mild
abnormal hemoglobin result, 1 (5%) subject experienced a maximum mild leukopenia result, and 1 (5%) subject experienced a maximum mild abnormal platelet result.

Seven (16%) subjects in the 18-55 age group experienced a maximum mild/grade 1 abnormal chemistry result post-vaccination, and 2 (4%) subjects experienced a maximum moderate/grade 2 abnormal chemistry result post-vaccination. Three (7%) subjects experienced a maximum mild abnormal alanine aminotransferase result, 1 (2%) subject experienced a maximum mild abnormal aspartate aminotransferase result, 2 (4%) subjects experienced a maximum mild abnormal bilirubin result and 1 (2%) subject experienced a maximum moderate bilirubin result. One (2%) subject experienced a maximum mild and 1 (2%) subject experienced a maximum moderate abnormal serum lipase result.

One (55%) subject in the 56-70 age group experienced a maximum mild/grade 1 abnormal chemistry result post-vaccination. This subject experienced a maximum mild abnormal aspartate aminotransferase result.

Two (10%) subjects in the 71+ age group experienced a maximum mild/grade 1 abnormal chemistry result post-vaccination. Both subjects experienced a maximum mild abnormal serum lipase result.

**Appendix F** includes a listing of vital signs for subjects who experience abnormal vital signs at any time post-vaccination.

5.7 **Protocol Adherence**

Tables 9A-9C summarizes the protocol deviations for this study by category and type. A full listing of protocol deviations is provided in **Appendix G**.

Among the subjects in the 18-55 years of age cohorts, a total of 23 deviations were reported in 19 subjects. There were 11 deviations reported for too few aliquots obtained, 5 for required procedure done incorrectly, 2 for required procedure not conducted, and one deviation each was reported for breach of confidentiality, out of window visit, non-required lab tests performed, and safety labs collected out of window.

Among the subjects in the 56-70 years of age cohorts, a total of 2 deviations were reported in 2 subjects. One deviation each was reported for missed visit/visit not conducted and too few aliquots obtained.

There were no deviations reported in the ≥71 years of age cohorts.

There was one non subject specific protocol deviation reported. A freezer storing the investigational product (IP) was out of range on April 17, 2020. The IP was immediately moved...
to a different freezer at the site. The study team was alerted of this and the site was instructed to continue use of the IP.

5.8 Pregnancies

A listing of pregnancies is provided in Appendix H. No pregnancies have been reported as of data cutoff.

6. TABLES AND FIGURES
### TABLE 2A:
Summary of Categorical Demographic and Baseline Characteristics
by Vaccination Group - All Subjects 18-55 Years of Age

<table>
<thead>
<tr>
<th>Demographic Category</th>
<th>Characteristic</th>
<th>25 mcg mRNA-1273 (N=15)</th>
<th></th>
<th>100 mcg mRNA-1273 (N=15)</th>
<th></th>
<th>250 mcg mRNA-1273 (N=15)</th>
<th></th>
<th>All Subjects (N=45)</th>
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<td>%</td>
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<td>3</td>
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<td>2</td>
<td>13</td>
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<td>.</td>
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### TABLE 2B:
Summary of Categorical Demographic and Baseline Characteristics
by Vaccination Group - All Subjects 56-70 Years of Age

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<thead>
<tr>
<th>Demographic Category</th>
<th>Characteristic</th>
<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
<th>All Subjects (N=20)</th>
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### TABLE 2C:
Summary of Categorical Demographic and Baseline Characteristics by Vaccination Group - All Subjects ≥71 Years of Age

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### TABLE 2D: Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group - All Subjects 18-55 Years of Age

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### TABLE 2E:
Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group - All Subjects 56-70 Years of Age

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<th>All Subjects (N=20)</th>
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TABLE 2F:
Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group - All Subjects ≥71 Years of Age

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## TABLE 2G:
Study Status: Number of Subjects Completing Study Milestones

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<th>Day 29</th>
<th>Day 30</th>
<th>Day 31</th>
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<td>25 mcg mRNA-1273 (18-55 years)</td>
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<td>15/15 (100%)</td>
<td>15/15 (100%)</td>
<td>15/15 (100%)</td>
<td>15/15 (100%)</td>
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<td>15/15 (100%)</td>
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<tr>
<td>250 mcg mRNA-1273 (18-55 years)</td>
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<td>15/15 (100%)</td>
<td>15/15 (100%)</td>
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<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
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<td>10/10 (100%)</td>
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<tr>
<td>100 mcg mRNA-1273 (56-70 years)</td>
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<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
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<td>10/10 (100%)</td>
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<tr>
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<td>0/10 (0%)</td>
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<td>85/85 (100%)</td>
<td>85/85 (100%)</td>
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Note: Percentages reflective of ongoing status of the trial.

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<td>0/15 (0%)</td>
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<td>250 mcg mRNA-1273 (18-55 years)</td>
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<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
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<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
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<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
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<tr>
<td>100 mcg mRNA-1273 (≥71 years)</td>
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<td>0/10 (0%)</td>
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<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
</tr>
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Note: Percentages reflective of ongoing status of the trial.
## TABLE 2H:
Subject Disposition Vaccination Group - All Subjects 18-55 Years of Age

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<td>100</td>
</tr>
<tr>
<td>Discontinued treatmenta</td>
<td>2</td>
<td>13</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Received the second vaccination</td>
<td>13</td>
<td>87</td>
<td>15</td>
<td>100</td>
</tr>
<tr>
<td>Discontinued treatmenta</td>
<td>2</td>
<td>13</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Study ongoing</td>
<td>15</td>
<td>100</td>
<td>15</td>
<td>100</td>
</tr>
<tr>
<td>Early terminationa</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Completed study</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
</tbody>
</table>

*aRefer to Table 2K for reasons subjects discontinued or terminated early.
## TABLE 2I:
Subject Disposition Vaccination Group - All Subjects 56-70 Years of Age

<table>
<thead>
<tr>
<th>Subject Disposition</th>
<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
<th>All Subjects (N=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Screened</td>
<td></td>
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</tr>
<tr>
<td>Enrolled</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Received the first vaccination</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Discontinued treatment&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.</td>
<td>.</td>
<td>1</td>
</tr>
<tr>
<td>Received the second vaccination</td>
<td>10</td>
<td>100</td>
<td>9</td>
</tr>
<tr>
<td>Discontinued treatment&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.</td>
<td>.</td>
<td>1</td>
</tr>
<tr>
<td>Study ongoing</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Early termination&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Completed study</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
</tbody>
</table>

<sup>a</sup>Refer to Table 2K for reasons subjects discontinued or terminated early.
### TABLE 2J:
Subject Disposition Vaccination Group - All Subjects ≥ 71 Years of Age

<table>
<thead>
<tr>
<th>Subject Disposition</th>
<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
<th>All Subjects (N=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Screened</td>
<td>-</td>
<td>.</td>
<td>-</td>
</tr>
<tr>
<td>Enrolled</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Received the first vaccination</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Discontinued treatment*</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Received the second vaccination</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Discontinued treatment*</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Study ongoing</td>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Early termination*</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Completed study</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
</tbody>
</table>

*Refer to Table 2K for reasons subjects discontinued or terminated early.
### TABLE 2K:
**Early Terminations or Discontinued Subjects**

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Vaccination Group</th>
<th>Enrollment Date</th>
<th>Reason for Treatment Discontinuation</th>
<th>Number of Vaccinations Received</th>
<th>Subject Terminated Early</th>
<th>Termination Date</th>
<th>Reason for Early Termination</th>
<th>Length of Time on Study (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mcg mRNA-1273 (18-55 years)</td>
<td>03/24/20</td>
<td>Became ineligible after enrollment, specify and enter eligibility criterion #: Subject has been exposed(in PPE) to someone with SARS-CoV-2 infection.</td>
<td>1</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>25 mcg mRNA-1273 (18-55 years)</td>
<td>03/24/20</td>
<td>Adverse event, other than serious adverse event, specify AE # 2 (HIVES ON LOWER EXTREMITIES)</td>
<td>1</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>250 mcg mRNA-1273 (18-55 years)</td>
<td>04/08/20</td>
<td>Adverse event, other than serious adverse event, specify AE # 2 (SORE THROAT)</td>
<td>1</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>100 mcg mRNA-1273 (56-70 years)</td>
<td>04/23/20</td>
<td>Adverse event, other than serious adverse event, specify AE # 2 (MACULOPAPULAR RASH)</td>
<td>1</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>
TABLE 3A:
Listing of Serious Adverse Events

No serious adverse events have been reported.
TABLE 3B: Listing of MAAEs and NOCMCs

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Vaccination Group</th>
<th>Event Description</th>
<th>Number of Doses Received at Time of Event</th>
<th>Date of Product Administration</th>
<th>Duration of Event</th>
<th>Date of Onset</th>
<th>MedDRA® System Organ Class</th>
<th>MAAEs</th>
<th>NOCMCs</th>
<th>Relationship</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (56-70 years)</td>
<td>Paronychia</td>
<td>01</td>
<td>23APR2020</td>
<td>2 (13)</td>
<td>25APR2020</td>
<td>Infections and infestations</td>
<td>Yes</td>
<td>No</td>
<td>Not related</td>
<td>Recovered /resolved</td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (56-70 years)</td>
<td>Maculopapular Rash</td>
<td>01</td>
<td>23APR2020</td>
<td>9 (Ongoing)</td>
<td>02MAY2020</td>
<td>Skin and subcutaneous tissue disorders</td>
<td>Yes</td>
<td>No</td>
<td>Not related</td>
<td>Recovering /resolving</td>
</tr>
<tr>
<td></td>
<td>250 mcg mRNA-1273 (18-55 years)</td>
<td>Sore Throat</td>
<td>01</td>
<td>08APR2020</td>
<td>24 (3)</td>
<td>02MAY2020</td>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Yes</td>
<td>No</td>
<td>Not related</td>
<td>Recovered /resolved</td>
</tr>
</tbody>
</table>

*aDate of most recent dose/product administration.

bRelated, Not Related.
TABLE 4A(i):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, Relationship to Study Vaccination, and Vaccination Group – 25 mcg mRNA-1273, 18-55 Years of Age (N=15)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>Severity</th>
<th>Not Related (n)</th>
<th>Related (n)</th>
<th>Not Yet Determined (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any SOC</td>
<td>Mild</td>
<td>20</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
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</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ear And Labyrinth Disorders</td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Eye Disorders</td>
<td>Mild</td>
<td>-</td>
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<td>-</td>
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<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>Mild</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>General Disorders And Administration Site Conditions</td>
<td>Mild</td>
<td>6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
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<tr>
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<td>Severe</td>
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</tr>
<tr>
<td>Infections And Infestations</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
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</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Injury, Poisoning And Procedural Complications</td>
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<tr>
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<td>Severe</td>
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<td>-</td>
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</tr>
<tr>
<td>Investigations</td>
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<td>Severe</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Metabolism And Nutrition Disorders</td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Musculoskeletal And Connective Tissue Disorders</td>
<td>Mild</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>
TABLE 4A(i):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, Relationship to Study Vaccination, and Vaccination Group – 25 mcg mRNA-1273, 18-55 Years of Age (N=15) (continued)

<table>
<thead>
<tr>
<th>MedDRA® System Organ Class</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System Disorders</td>
<td></td>
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</tr>
<tr>
<td>Psychiatric Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive System And Breast Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory, Thoracic And Mediastinal Disorders</td>
<td></td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Skin And Subcutaneous Tissue Disorders</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
TABLE 4A(ii):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>Severity</th>
<th>Relationship to Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Cardiac Disorders</td>
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</tr>
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<td></td>
<td>Moderate</td>
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</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
</tr>
<tr>
<td>Ear And Labyrinth Disorders</td>
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</tr>
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<td></td>
<td>Moderate</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
</tr>
<tr>
<td>Eye Disorders</td>
<td>Mild</td>
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</tr>
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<td></td>
<td>Moderate</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
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</tr>
<tr>
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<td>Moderate</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
</tr>
<tr>
<td>General Disorders And Administration Site Conditions</td>
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<td>Severe</td>
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</tr>
<tr>
<td>Infections And Infestations</td>
<td>Mild</td>
<td>-</td>
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<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
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</tr>
<tr>
<td>Injury, Poisoning And Procedural Complications</td>
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<td></td>
<td>Moderate</td>
<td>1</td>
</tr>
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</tr>
<tr>
<td></td>
<td>Severe</td>
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</tr>
<tr>
<td>Metabolism And Nutrition Disorders</td>
<td>Mild</td>
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</tr>
<tr>
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<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
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</tr>
<tr>
<td>Musculoskeletal And Connective Tissue Disorders</td>
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</table>
# TABLE 4A-ii:
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, Relationship to Study Vaccination, and Vaccination Group – 100 mcg mRNA-1273, 18-55 Years of Age (N=15) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>Severity</th>
<th>Not Related (n)</th>
<th>Related (n)</th>
<th>Not Yet Determined (n)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>Mild</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
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<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
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</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Reproductive System And Breast Disorders</td>
<td>Mild</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Respiratory, Thoracic And Mediastinal Disorders</td>
<td>Mild</td>
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<td>1</td>
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<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Skin And Subcutaneous Tissue Disorders</td>
<td>Mild</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vascular Disorders</td>
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<td>-</td>
<td>1</td>
<td>-</td>
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<tr>
<td></td>
<td>Moderate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
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</tr>
</tbody>
</table>
TABLE 4A(iii):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>Severity</th>
<th>Relationship to Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Not Related (n)</td>
</tr>
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<td>Any SOC</td>
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TABLE 4A(iii):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, Relationship to Study Vaccination, and Vaccination Group – 250 mcg mRNA-1273, 18-55 Years of Age (N=15) (continued)

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TABLE 4A(iv):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and Vaccination Group – All Subjects 18-55 years (N=45) (continued)

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TABLE 4B(i):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10) (continued)

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## TABLE 4B(ii):
### All Adverse Events Cross-Classified by
### MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
### Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10)

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All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and Vaccination Group – All Subjects 56-70 years (N=20)

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### TABLE 4B(iii):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Vaccination Group – All Subjects 56-70 years (N=20) (continued)

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### TABLE 4C(i):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10) (continued)

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### TABLE 4C(ii):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10) (continued)

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TABLE 4C(iii):
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Vaccination Group – All Subjects ≥71 years (N=20)

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## TABLE 4C(iii):
All Adverse Events Cross-Classified by MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and Vaccination Group – All Subjects ≥71 years (N=20) (continued)

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FIGURE 1A:
Number and Severity of All Adverse Events by MedDRA System Organ Class and Vaccination Group - 18-55 Years of Age
FIGURE 1B:
Number and Severity of All Adverse Events by MedDRA System Organ Class and Vaccination Group – 56-70 Years of Age
FIGURE 1C:
Number and Severity of All Adverse Events by MedDRA System Organ Class and Vaccination Group – ≥ 71 Years of Age
TABLE 4D(i):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 years (N=15)

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TABLE 4D(i):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 years (N=15) (continued)

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### TABLE 4D(ii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15)

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TABLE 4D(ii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) (continued)

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**TABLE 4D(iii):**
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15)

<table>
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<td>Gastrointestinal disorders</td>
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### TABLE 4D(iii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)

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<th>Relationship to Study Vaccination</th>
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### TABLE 4D(iv):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group –mRNA-1273 All Subjects 18-55 years (N=45)

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<th>Relationship to Study Vaccination</th>
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### TABLE 4D(iv):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=45) (continued)

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</table>
TABLE 4D(iv):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=45) (continued)

<p>| Reproductive system and breast disorders | Any PT | 3 | 3 | - | - | 2 | 1 | - |
| Breast pain | 1 | 1 | - | - | 1 | - | - |
| Vaginal haemorrhage | 1 | 1 | - | - | - | 1 | - |
| Vulvovaginal pruritus | 1 | 1 | - | - | 1 | - | - |
| Respiratory, thoracic and mediastinal disorders | Any PT | 7 | 7 | - | - | 5 | 2 | - |
| Diaphragmatic spasm | 1 | 1 | - | - | - | 1 | - |
| Dyspnoea exertional | 1 | 1 | - | - | 1 | - | - |
| Nasal congestion | 1 | 1 | - | - | 1 | - | - |
| Oropharyngeal pain | 4 | 4 | - | - | 3 | 1 | - |
| Skin and subcutaneous tissue disorders | Any PT | 6 | 4 | 2 | - | 2 | 4 | - |
| Dermatitis contact | 1 | 1 | - | - | 1 | - | - |
| Erythema | 1 | 1 | - | - | 1 | - | - |
| Hyperhidrosis | 1 | - | 1 | - | - | 1 | - |
| Night sweats | 1 | - | 1 | - | - | 1 | - |
| Petechiae | 1 | 1 | - | - | - | 1 | - |
| Urticaria | 1 | 1 | - | - | - | 1 | - |
| Vascular disorders | Any PT | 4 | 4 | - | - | 3 | 1 | - |
| Hypertension | 1 | 1 | - | - | 1 | - | - |
| Hypotension | 1 | 1 | - | - | 1 | - | - |
| Systolic hypertension | 1 | 1 | - | - | 1 | - | - |
| Vasodilatation | 1 | 1 | - | - | - | 1 | - |</p>
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<th>Moderate (n)</th>
<th>Severe (n)</th>
<th>Not Related (n)</th>
<th>Related (n)</th>
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### TABLE 4E(ii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10)

<table>
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<tr>
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<th>Relationship to Study Vaccination</th>
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<td>Infections and infestations</td>
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<td>1</td>
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<tr>
<td></td>
<td>Rash maculo-papular</td>
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</tr>
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<td>Vascular disorders</td>
<td>Systolic hypertension</td>
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### TABLE 4E(iii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=20)

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<th>Moderate (n)</th>
<th>Severe (n)</th>
<th>Not Related (n)</th>
<th>Related (n)</th>
<th>Not Yet Determined (n)</th>
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<td>Vertigo</td>
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<td>1</td>
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<td>-</td>
<td>-</td>
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<tr>
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<td>2</td>
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<td>-</td>
<td>2</td>
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<td>Vaccination site bruising</td>
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<td>1</td>
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<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Exposure via inhalation</td>
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<td>1</td>
<td>-</td>
<td>1</td>
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<td>-</td>
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**TABLE 4E(iii):**
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=20) *(continued)*

<table>
<thead>
<tr>
<th>System Organ Class (SOC)</th>
<th>Preferred Term (PT)</th>
<th>Total Events (n)</th>
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<th>Moderate (n)</th>
<th>Severe (n)</th>
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<th>Related (n)</th>
<th>Not Yet Determined (n)</th>
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### TABLE 4F(i):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10)

<table>
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<tr>
<th>System Organ Class (SOC)</th>
<th>Preferred Term (PT)</th>
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<th>Severity</th>
<th>Relationship to Study Vaccination</th>
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<td>Moderate (n)</td>
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<td>Energy increased</td>
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</tr>
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<td>Arthropod bite</td>
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<td>Skin abrasion</td>
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<tr>
<td></td>
<td>Sunburn</td>
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<td></td>
<td>Joint swelling</td>
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<td></td>
<td>Musculoskeletal chest pain</td>
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<td>Nervous system disorders</td>
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<td>Pruritus</td>
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### TABLE 4F(ii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10)

<table>
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<th>Moderate (n)</th>
<th>Severe (n)</th>
<th>Not Related (n)</th>
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<td>-</td>
<td>-</td>
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<td>-</td>
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<td>Vessel puncture site bruise</td>
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<td>-</td>
<td>-</td>
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### TABLE 4F(iii):
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=20)

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<td></td>
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<td>Night sweats</td>
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<td>Pruritus</td>
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### TABLE 4G(i):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 Years of Age (N=15)

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<th>Severity</th>
<th>Relationship to Study Vaccination</th>
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<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
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<td></td>
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<tr>
<td></td>
<td>Injection site irritation</td>
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<td>Injury, poisoning and procedural complications</td>
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<td></td>
<td>Contusion</td>
<td>2</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Muscle strain</td>
<td>2</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Skin abrasion</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Skin laceration</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Muscular weakness</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Presyncope</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Any PT</td>
<td>2</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Dyspnoea exertional</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Oropharyngeal pain</td>
<td>1</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>
### TABLE 4G(i):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 Years of Age (N=15) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Any PT</td>
<td>4 27</td>
<td>4 27</td>
<td>-</td>
<td>-</td>
<td>2 13</td>
<td>2 13</td>
</tr>
<tr>
<td></td>
<td>Dermatitis contact</td>
<td>1 7</td>
<td>1 7</td>
<td>-</td>
<td>-</td>
<td>1 7</td>
<td>- -</td>
</tr>
<tr>
<td></td>
<td>Erythema</td>
<td>1 7</td>
<td>1 7</td>
<td>-</td>
<td>-</td>
<td>1 7</td>
<td>- -</td>
</tr>
<tr>
<td></td>
<td>Petechiae</td>
<td>1 7</td>
<td>1 7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- -</td>
</tr>
<tr>
<td></td>
<td>Urticaria</td>
<td>1 7</td>
<td>1 7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- -</td>
</tr>
<tr>
<td></td>
<td>Systolic hypertension</td>
<td>1 7</td>
<td>1 7</td>
<td>-</td>
<td>-</td>
<td>1 7</td>
<td>- -</td>
</tr>
</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
**TABLE 4G(ii):**
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any SOC</td>
<td>Any PT</td>
<td>10</td>
<td>67</td>
<td>9</td>
<td>60</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Bradycardia</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Eye irritation</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Abdominal discomfort</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Faeces discoloured</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Any PT</td>
<td>4</td>
<td>27</td>
<td>4</td>
<td>27</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Feeling jittery</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Injection site bruising</td>
<td>3</td>
<td>20</td>
<td>3</td>
<td>20</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Injection site pruritus</td>
<td>2</td>
<td>13</td>
<td>2</td>
<td>13</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Any PT</td>
<td>3</td>
<td>20</td>
<td>2</td>
<td>13</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Muscle strain</td>
<td>2</td>
<td>13</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Thermal burn</td>
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<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Investigations</td>
<td>Heart rate increased</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Decreased appetite</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Neck pain</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
**TABLE 4G(ii):**
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) *(continued)*

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive system and breast disorders</td>
<td>Breast pain</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Any PT</td>
<td>3</td>
<td>20</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Diaphragmatic spasm</td>
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<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Nasal congestion</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Oropharyngeal pain</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Vasodilatation</td>
<td>1</td>
<td>7</td>
<td>-</td>
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</tr>
</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
TABLE 4G(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and
Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15)

<table>
<thead>
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<th>MedDRA System Organ Class</th>
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<th></th>
<th></th>
<th>Relationship to Study Vaccination</th>
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</thead>
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<td></td>
<td>Any Incidence</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Not Related</td>
</tr>
<tr>
<td>Any SOC</td>
<td>Any PT</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Bradycardia</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Scintillating scotoma</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Any PT</td>
<td>3</td>
<td>20</td>
<td>3</td>
<td>20</td>
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</tr>
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<td>Abdominal pain upper</td>
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<td>7</td>
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</tr>
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<td></td>
<td>Lip disorder</td>
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<td>7</td>
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<td></td>
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<td>1</td>
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<td>General disorders and</td>
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<td>20</td>
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<td>13</td>
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</tr>
<tr>
<td>administration site</td>
<td></td>
<td></td>
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<td>Injection site pruritus</td>
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<td>7</td>
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<td>7</td>
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</tr>
<tr>
<td></td>
<td>Malaise</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
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</tr>
<tr>
<td></td>
<td>Vessel puncture site</td>
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<td>bruise</td>
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<td>Metabolism and nutrition</td>
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<td>27</td>
<td>1</td>
<td>7</td>
<td>3</td>
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<td>disorders</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreased appetite</td>
<td>3</td>
<td>20</td>
<td>1</td>
<td>7</td>
<td>2</td>
</tr>
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<td></td>
<td>Hypoglycaemia</td>
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<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
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<td>Musculoskeletal and</td>
<td>Any PT</td>
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<td>20</td>
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<td>7</td>
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</tr>
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<td>connective tissue</td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Muscle spasms</td>
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<td>7</td>
<td>-</td>
<td>-</td>
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</tr>
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</table>
### TABLE 4G(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Muscle strain</td>
<td></td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Any PT</td>
<td>3</td>
<td>20</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>2</td>
<td>13</td>
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<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Syncope</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
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<td>-</td>
</tr>
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<td>-</td>
</tr>
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<td></td>
<td>Anxiety</td>
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<td>7</td>
<td>1</td>
<td>7</td>
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<td>-</td>
</tr>
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<td>Insomnia</td>
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<td>7</td>
<td>1</td>
<td>7</td>
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<td>-</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>Any PT</td>
<td>2</td>
<td>13</td>
<td>2</td>
<td>13</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Vaginal haemorrhage</td>
<td>1</td>
<td>7</td>
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<td>7</td>
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<td></td>
<td>Vulvovaginal pruritus</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Oropharyngeal pain</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Any PT</td>
<td>2</td>
<td>13</td>
<td>-</td>
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<td>2</td>
<td>13</td>
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<td>Hyperhidrosis</td>
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</tr>
<tr>
<td></td>
<td>Night sweats</td>
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<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Any PT</td>
<td>2</td>
<td>13</td>
<td>2</td>
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<td>Hypertension</td>
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<td>7</td>
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</tr>
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<td>Hypotension</td>
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<td>7</td>
<td>1</td>
<td>7</td>
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<td>-</td>
</tr>
</tbody>
</table>
### TABLE 4G(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
### TABLE 4G(iv):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 18-55 years (N=45)

<table>
<thead>
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<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Severity</th>
<th>Relationship to Study Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Any SOC</td>
<td>Any PT</td>
<td>32</td>
<td>71</td>
<td>27</td>
<td>60</td>
<td>12</td>
<td>27</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Bradycardia</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Eye disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Eye irritation</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Scintillating scotoma</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
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### TABLE 4G(iv):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and
Vaccination Group – 18-55 years (N=45) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Severity</th>
<th>Relationship to Study Vaccine</th>
<th>Vaccination</th>
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<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
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<td>Malaise</td>
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<td>Vessel puncture site bruise</td>
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<td>3</td>
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<tr>
<td>Metabolism and nutrition disorders</td>
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<td>11</td>
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<td>Decreased appetite</td>
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<td>4</td>
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<td>Hypoglycaemia</td>
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</tr>
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<td>Musculoskeletal and connective tissue disorders</td>
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<td>Muscle strain</td>
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<td>Muscular weakness</td>
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### TABLE 4G(iv):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 18-55 years (N=45) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Severity</th>
<th>Relationship to Study Vaccination</th>
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<td></td>
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<td>Any Incidence</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
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<td></td>
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<td>n</td>
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<td>2</td>
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<td><strong>Any PT</strong></td>
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<td>11</td>
<td>3</td>
<td>7</td>
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<td>2</td>
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<td><strong>Headache</strong></td>
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<td>4</td>
<td>1</td>
<td>2</td>
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<tr>
<td><strong>Presyncope</strong></td>
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<td>2</td>
<td>1</td>
<td>2</td>
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<tr>
<td><strong>Syncope</strong></td>
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<td>2</td>
<td>1</td>
<td>2</td>
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<tr>
<td><strong>Psychiatric disorders</strong></td>
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<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Any PT</strong></td>
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<td>1</td>
<td>2</td>
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<td><strong>Insomnia</strong></td>
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<td>2</td>
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<td>2</td>
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<td><strong>Reproductive system and breast disorders</strong></td>
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<td><strong>Breast pain</strong></td>
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<td>2</td>
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<tr>
<td><strong>Vaginal haemorrhage</strong></td>
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<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
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<td>13</td>
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<td><strong>Any PT</strong></td>
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<td><strong>Diaphragmatic spasm</strong></td>
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<td><strong>Dyspnoea exertional</strong></td>
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<td>1</td>
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<td><strong>Nasal congestion</strong></td>
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<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Oropharyngeal pain</strong></td>
<td>3</td>
<td>7</td>
<td>3</td>
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</tbody>
</table>

| **Any PT**                      | 6                     | 13            | 4         | 9        | 2      | 4            | 2        |

Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
### TABLE 4G(iv):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 18-55 years (N=45) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Severity</th>
<th>Relationship to Study Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Dermatitis contact</td>
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<td>2</td>
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<tr>
<td></td>
<td>Erythema</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hyperhidrosis</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Night sweats</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urticaria</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Any PT</td>
<td>4</td>
<td>9</td>
<td></td>
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<tr>
<td></td>
<td>Hypertension</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
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<td></td>
<td>Hypotension</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic hypertension</td>
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<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vasodilatation</td>
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Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
TABLE 4H(i):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10)

<table>
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<th>Severity</th>
<th>Relationship to Study Vaccination</th>
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<td></td>
<td>n</td>
<td>%</td>
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<tr>
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<td>80</td>
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<td>Any PT</td>
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<td>20</td>
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<tr>
<td>Injection site bruising</td>
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<td>1</td>
</tr>
<tr>
<td>Vaccination site bruising</td>
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<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Exposure via inhalation</td>
<td>1</td>
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</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Decreased appetite</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Any PT</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Headache</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Sciatica</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Insomnia</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Oropharyngeal pain</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Diastolic hypertension</td>
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Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
TABLE 4H(ii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10)

<table>
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<th>Moderate</th>
<th>Severe</th>
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<th>Related</th>
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<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Infections and infestations</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
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<td></td>
<td></td>
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<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
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<td></td>
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<td>Vascular disorders</td>
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</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
TABLE 4H(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=20)

<table>
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<th>Severity</th>
<th>Relationship to Study Vaccination</th>
</tr>
</thead>
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<td></td>
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<td>%</td>
<td>n</td>
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<td>Any PT</td>
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<td>70</td>
<td>10</td>
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<td>5</td>
<td>-</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Any PT</td>
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<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Injection site bruising</td>
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<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Vaccination site bruising</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
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<td>Infections and infestations</td>
<td>Paronychia</td>
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</tr>
<tr>
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<td>Exposure via inhalation</td>
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<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
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<td>10</td>
<td>-</td>
</tr>
<tr>
<td>Decreased appetite</td>
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<td>Hypoglycaemia</td>
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<td>-</td>
</tr>
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<td>Nervous system disorders</td>
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<td>2</td>
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<td>Headache</td>
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<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Sciatica</td>
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<td>5</td>
<td>1</td>
<td>5</td>
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<td>Psychiatric disorders</td>
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</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
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<tr>
<td>Nasal congestion</td>
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<td>5</td>
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<td>-</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
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<td>10</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
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</table>
TABLE 4H(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=20) (continued)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diastolic hypertension</td>
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<td>5</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic hypertension</td>
<td>1</td>
<td>5</td>
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</tr>
</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Severity</th>
<th>Relationship to Study Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Any SOC</td>
<td>Any PT</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Any PT</td>
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<td>20</td>
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<tr>
<td></td>
<td>Energy increased</td>
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<td>Injection site bruising</td>
<td>1</td>
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<td>1</td>
</tr>
<tr>
<td></td>
<td>Any PT</td>
<td>3</td>
<td>30</td>
<td>3</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Arthropod bite</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Skin abrasion</td>
<td>2</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Sunburn</td>
<td>1</td>
<td>10</td>
<td>1</td>
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<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Any PT</td>
<td>2</td>
<td>20</td>
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</tr>
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<td></td>
<td>Joint swelling</td>
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<tr>
<td></td>
<td>Musculoskeletal chest pain</td>
<td>1</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Night sweats</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Pruritus</td>
<td>1</td>
<td>10</td>
<td>1</td>
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</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
TABLE 4I(ii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any SOC</td>
<td>Any PT</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Any PT</td>
<td>2</td>
<td>20</td>
<td>2</td>
<td>20</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Injection site bruising</td>
<td></td>
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<td>10</td>
<td>1</td>
<td>10</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vessel puncture site bruise</td>
<td></td>
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<td>20</td>
<td>2</td>
<td>20</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Dermatitis</td>
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<td>10</td>
<td>1</td>
<td>10</td>
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<td>-</td>
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</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
### TABLE 4I(iii):
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=20)

<table>
<thead>
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<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Severity</th>
<th></th>
<th></th>
<th>Relationship to Study Vaccination</th>
</tr>
</thead>
<tbody>
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<td></td>
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<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
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<td>Any PT</td>
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<td>5</td>
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<td>Any PT</td>
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<td>20</td>
<td>4</td>
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</tr>
<tr>
<td>Energy increased</td>
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<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Injection site bruising</td>
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<td>10</td>
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<tr>
<td>Vessel puncture site bruise</td>
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<td>2</td>
<td>10</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Any PT</td>
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<td>15</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Arthropod bite</td>
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<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Skin abrasion</td>
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<td>2</td>
<td>10</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Sunburn</td>
<td></td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Any PT</td>
<td>2</td>
<td>10</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Joint swelling</td>
<td></td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Musculoskeletal chest pain</td>
<td></td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
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<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
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<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Any PT</td>
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<td>15</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Dermatitis</td>
<td></td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
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<tr>
<td>Night sweats</td>
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<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>
**TABLE 4I(iii):**
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=20) *(continued)*

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Any Incidence</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Not Related</th>
<th>Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus</td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.
FIGURE 2A(i):
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 18-55 Years of Age
FIGURE 2A(ii):
Maximum Severity of Solicited Events by Symptom and Vaccination Group – Local - 18-55 Years of Age
Figure 2B(i):
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 56-70 Years of Age
Figure 2B(ii):
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local - 56-70 Years of Age

-87-
Figure 2C(i):
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - ≥71 Years of Age

<table>
<thead>
<tr>
<th>Symptom</th>
<th>25 mcg mRNA-1273 ≥71 years (N=10)</th>
<th>100 mcg mRNA-1273 ≥71 years (N=10)</th>
<th>≥71 years (N=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Systemic</td>
<td>5/10</td>
<td>3/10</td>
<td>5/20</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1/10</td>
<td>6/10</td>
<td>1/20</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2/10</td>
<td>3/10</td>
<td>2/20</td>
</tr>
<tr>
<td>Fever</td>
<td>6/10</td>
<td>6/10</td>
<td>0/20</td>
</tr>
<tr>
<td>Feverishness</td>
<td>6/10</td>
<td>6/10</td>
<td>0/20</td>
</tr>
<tr>
<td>Headache</td>
<td>3/10</td>
<td>6/10</td>
<td>3/20</td>
</tr>
<tr>
<td>Myalgia</td>
<td>3/10</td>
<td>2/10</td>
<td>5/20</td>
</tr>
<tr>
<td>Nausea</td>
<td>6/10</td>
<td>6/10</td>
<td>0/20</td>
</tr>
</tbody>
</table>

Percent of Subjects (%)
Figure 2C(ii):
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local - ≥71 Years of Age
### TABLE 5A(i):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group - Any Symptom - 18-55 Years of Age

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Dose 1</th>
<th></th>
<th></th>
<th>Dose 2</th>
<th></th>
<th></th>
<th>All Subjects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Symptom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5</td>
<td>33.3</td>
<td>1</td>
<td>6.7</td>
<td></td>
<td></td>
<td>6</td>
<td>13.3</td>
</tr>
<tr>
<td>Mild</td>
<td>8</td>
<td>53.3</td>
<td>10</td>
<td>66.7</td>
<td>9</td>
<td>60</td>
<td>27</td>
<td>60</td>
</tr>
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<td>Moderate</td>
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<td>13.3</td>
<td>3</td>
<td>20</td>
<td>5</td>
<td>33.3</td>
<td>10</td>
<td>22.2</td>
</tr>
<tr>
<td>Severe</td>
<td>-</td>
<td>-</td>
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<td>6.7</td>
<td>1</td>
<td>6.7</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Dose 2</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>3</td>
<td>23.1</td>
<td></td>
<td>-</td>
<td>-</td>
<td></td>
<td>3</td>
<td>7.1</td>
</tr>
<tr>
<td>Mild</td>
<td>7</td>
<td>53.8</td>
<td>3</td>
<td>20</td>
<td>1</td>
<td>7.1</td>
<td>11</td>
<td>26.2</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>23.1</td>
<td>11</td>
<td>73.3</td>
<td>9</td>
<td>64.3</td>
<td>23</td>
<td>54.8</td>
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<td>-</td>
<td>-</td>
<td>1</td>
<td>6.7</td>
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<td>5</td>
<td>11.9</td>
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<td>26.7</td>
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<td>-</td>
<td>-</td>
<td></td>
<td>4</td>
<td>8.9</td>
</tr>
<tr>
<td>Mild</td>
<td>6</td>
<td>40</td>
<td>3</td>
<td>20</td>
<td>1</td>
<td>6.7</td>
<td>10</td>
<td>22.2</td>
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<td>5</td>
<td>33.3</td>
<td>11</td>
<td>73.3</td>
<td>10</td>
<td>66.7</td>
<td>26</td>
<td>57.8</td>
</tr>
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<td>-</td>
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<td>6.7</td>
<td>4</td>
<td>26.7</td>
<td>5</td>
<td>11.1</td>
</tr>
</tbody>
</table>

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
### TABLE 5A(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 18-55 Years of Age

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Dose</th>
<th>Severity</th>
<th>25 mcg mRNA-1273 (N=15)</th>
<th>100 mcg mRNA -1273 (N=15)</th>
<th>250 mcg mRNA -1273 (N=15)</th>
<th>All Subjects (N=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Any Systemic Symptom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>None</td>
<td>10</td>
<td>10</td>
<td>66.7</td>
<td>5</td>
<td>33.3</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>3</td>
<td>20</td>
<td></td>
<td>8</td>
<td>53.3</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>2</td>
<td>13.3</td>
<td></td>
<td>2</td>
<td>13.3</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Dose 2</td>
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<td>46.2</td>
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<td>-</td>
<td></td>
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</tr>
<tr>
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<td>33.3</td>
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<td>12</td>
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</tr>
<tr>
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<td></td>
<td></td>
<td>-</td>
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<td></td>
<td>13</td>
<td>86.7</td>
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<td>84.6</td>
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<td>6.7</td>
</tr>
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<td>15.4</td>
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<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
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<td></td>
</tr>
<tr>
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<td>13</td>
<td>86.7</td>
<td></td>
<td>13</td>
<td>86.7</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
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<td></td>
<td>-</td>
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</tr>
<tr>
<td></td>
<td>Moderate</td>
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<td>15.4</td>
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<td>6.7</td>
</tr>
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<td>Severe</td>
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<td></td>
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<td></td>
</tr>
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<td>Dose 2</td>
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<td>86.7</td>
<td></td>
<td>13</td>
<td>86.7</td>
</tr>
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<td>6.7</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>-</td>
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</tr>
</tbody>
</table>

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES

Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
TABLE 5A(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 18-55 Years of Age (continued)

<table>
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TABLE 5A(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and
Vaccination Group – Systemic Symptoms - 18-55 Years of Age (continued)

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### TABLE 5A(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 18-55 Years of Age (continued)

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Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 18-55 Years of Age (continued)

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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
*Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.
### TABLE 5A(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age

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### TABLE 5A(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age (continued)

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TABLE 5A(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age (continued)

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TABLE 5A(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age (continued)

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<th>100 mcg mRNA -1273 (N=15)</th>
<th>250 mcg mRNA -1273 (N=15)</th>
<th>All Subjects (N=45)</th>
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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
### TABLE 5B(i):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - 56-70 Years of Age

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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject. N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
TABLE 5B(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age

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### TABLE 5B(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age (continued)

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TABLE 5B(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age (continued)

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### TABLE 5B(ii):  
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age (continued)

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### TABLE 5B(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age (continued)

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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
*Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.
### TABLE 5B(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age

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DMID Protocol 20-0003
Safety Summary Report
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Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age (continued)

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### TABLE 5B(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age (continued)

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### TABLE 5B(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age (continued)

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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
### TABLE 5C(i):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - ≥71 years of Age

<table>
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<tr>
<th>Symptom</th>
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<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
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<tr>
<td></td>
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<td>Severe</td>
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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
**TABLE 5C(ii):**
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - ≥71 years of Age

<table>
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<th>Symptom</th>
<th>Dose</th>
<th>Severity</th>
<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
<th>All Subjects (N=20)</th>
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TABLE 5C(ii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - ≥71 years of Age (continued)

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<tr>
<th>Symptom</th>
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<th>25 mcg mRNA-1273 (N=10)</th>
<th>100 mcg mRNA-1273 (N=10)</th>
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</table>

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.
*Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.
### TABLE 5C(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - ≥71 years of Age

<table>
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Severity is the maximum severity reported over all solicited symptoms post dosing for each subject. N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

TABLE 5C(iii):
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - ≥71 years of Age (continued)
FIGURE 3A(i):
Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group - 18-55 Years of Age
FIGURE 3A(ii):
Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group – 56-70 Years of Age

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<th>Vaccination Day</th>
<th>Pre-Dose</th>
<th>25 mcg mRNA-1273 56-70 years (N=10)</th>
<th>100 mcg mRNA-1273 56-70 years (N=10)</th>
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Percent of Subjects (%)

- Mild
- Moderate
- Severe
FIGURE 3A(iii):
Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group - ≥71 Years of Age
## TABLE 6A(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 25 mcg mRNA-1273 (18-55 years)**

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Data Cutoff Date: 25MAY2020
Report Date: 02JUN2020

PREPARED BY EMMES
TABLE 6A(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (18-55 years) (continued)

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TABLE 6A(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
## TABLE 6A(ii):
### Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
#### Dose Number = Dose 2
**Vaccination Group – 25 mcg mRNA-1273 (18-55 years)**

### Symptom Severity

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### TABLE 6A(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (18-55 years) *(continued)*

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TABLE 6A(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 25 mcg mRNA-1273 (18-55 years) *(continued)*

| Severe | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Not Reported | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | NA | NA |

Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
**TABLE 6A(iii):**
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Any Dose
Vaccination Group – 25 mcg mRNA-1273 (18-55 years)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
### TABLE 6A(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

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### TABLE 6A(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (18-55 years)** *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6B(i):

**Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Dose 1**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)**

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# TABLE 6B(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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TABLE 6B(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 100 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
## TABLE 6B(ii):
### Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 2**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)**

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## TABLE 6B(ii):
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#### Vaccination Group – 100 mcg mRNA-1273 (18-55 years) (continued)

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*PRIVILEGED AND CONFIDENTIAL COMMUNICATION*  
**PREPARED BY EMMES**
TABLE 6B(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 100 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
TABLE 6B(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 100 mcg mRNA-1273 (18-55 years)

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### TABLE 6B(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)** (continued)

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### TABLE 6B(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)** *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6C(i):

**Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Dose 1**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)**

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Data Cutoff Date: 25MAY2020
Report Date: 02JUN2020
### TABLE 6C(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
**TABLE 6C(i):**

Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

Dose Number = Dose 1

Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
TABLE 6C(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 250 mcg mRNA-1273 (18-55 years)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 6C(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

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**Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
TABLE 6C(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.

a The data for Day 7 and Day 8 following the second vaccination for 2 subjects in Cohort 3 was entered after the time of data cutoff; there were no graded events entered for these 2 subjects for this day.

b Data for Day 8 following the second vaccination for 1 subject in Cohort 3 was confirmed as not available by the site.
### TABLE 6C(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

*Privileged and Confidential Communication*

*Prepared by Emmeis*
TABLE 6C(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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### TABLE 6C(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

TABLE 6D(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (56-70 years)
### TABLE 6D(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (56-70 years)

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TABLE 6D(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (56-70 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
**TABLE 6D(ii):**  
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group  
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Vaccination Group – 25 mcg mRNA-1273 (56-70 years)

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TABLE 6D(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (56-70 years) (continued)

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### TABLE 6D(ii):
**Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Dose 2**

**Vaccination Group – 25 mcg mRNA-1273 (56-70 years)** *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
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### TABLE 6D(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (56-70 years)** *(continued)*

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 6D(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (56-70 years)** (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

"Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6E(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

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**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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### TABLE 6E(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
TABLE 6E(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6E(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 2**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
## TABLE 6E(ii):
### Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
**Dose Number = Dose 2**
**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**
(continued)

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TABLE 6E(ii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6E(iii):

**Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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Data Cutoff Date: 25MAY2020

Report Date: 02JUN2020
### TABLE 6E(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (continued)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 6E(iii):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Any Dose
Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
TABLE 6F(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (≥71 years)

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### TABLE 6F(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 25 mcg mRNA-1273 (≥71 years)**

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Severity is the maximum severity reported post dosing for each subject for each day.

"Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
TABLE 6G(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group

Dose Number = Dose 1
Vaccination Group – 100 mcg mRNA-1273 (≥71 years)

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**TABLE 6G(i):**
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 100 mcg mRNA-1273 (≥71 years) *(continued)*

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Data Cutoff Date: 25MAY2020
TABLE 6G(i):
Summary of Systemic Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 100 mcg mRNA-1273 (≥71 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
TABLE 6H(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Dose 1

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

DMID Protocol 20-0003
Safety Summary Report

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
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Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
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### TABLE 6H(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Dose 1 (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6H(ii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
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### TABLE 6H(ii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.

* The data for Day 7 and Day 8 following the second vaccination for 2 subjects in Cohort 3 was entered after the time of data cutoff; there were no graded events entered for these 2 subjects for these days.

b Data for Day 8 following the second vaccination for 1 subject in Cohort 3 was confirmed as not available by the site.
### TABLE 6H(iii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Any Dose

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
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Data Cutoff Date: 25MAY2020

DMID Protocol 20-0003
Safety Summary Report

Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMDES
### TABLE 6H(iii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Any Dose (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6I(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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TABLE 6i(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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TABLE 61(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
Dose Number = Dose 1 (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6(ii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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*Any Post-Dose = Dose Number = Dose 2

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Data Cutoff Date: 25MAY2020

Report Date: 02JUN2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
TABLE 6I(ii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
Dose Number = Dose 2 (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6I(iii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
Dose Number = Any Dose

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Data Cutoff Date: 25MAY2020
TABLE 6I(iii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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### TABLE 6I(iii):
Summary of Systemic Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
### TABLE 6J(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day ≥71 years of Age:
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### TABLE 6J(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day ≥71 years of Age:
Dose Number = Dose 1 (continued)

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**Data Cutoff Date:** 25MAY2020

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### TABLE 6J(i):
Summary of Systemic Solicited Events for All Vaccination Groups by Day ≥71 years of Age:
Dose Number = Dose 1 (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

See Appendix D for listing of attributions for systemic events contributing toward halting criteria.
FIGURE 4A:
Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age
FIGURE 4B:
Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age

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Percent of Subjects (%)

Mild  Moderate  Severe
FIGURE 4C:
Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group ≥71 Years of Age
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TABLE 7A(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
**TABLE 7A(ii):**
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 25 mcg mRNA-1273 (18-55 years)

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TABLE 7A(ii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 25 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7A(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (18-55 years)**

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# TABLE 7A(iii):
## Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
### Dose Number = Any Dose
#### Vaccination Group – 25 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
## TABLE 7B(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)**

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Data Cutoff Date: 25MAY2020
Report Date: 02JUN2020
# TABLE 7B(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

## Dose Number = Dose 1

Vaccination Group – 100 mcg mRNA-1273 (18-55 years) *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7B(ii):  
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group  
Dose Number = Dose 2  
Vaccination Group – 100 mcg mRNA-1273 (18-55 years)

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| Erythema/Redness         |          |                  |              |              |              |              |              |              |              |              |                |
| None                     |          | 15 (100)         | 15 (100)     | 13 (87)      | 14 (93)      | 14 (93)      | 14 (93)      | 14 (93)      | 15 (100)     | 15 (100)     | 15 (100)       |
| Mild                     |          | -                | -            | 2 (13)       | 1 (7)        | 1 (7)        | 1 (7)        | 1 (7)        | -            | -            | 2 (13)        |
| Moderate                 |          | -                | -            | -            | -            | -            | -            | -            | -            | -            | -              |
| Severe                   |          | -                | -            | -            | -            | -            | -            | -            | -            | -            | -              |
| Not Reported             |          | -                | -            | -            | -            | -            | -            | -            | -            | -            | -              |

| Erythema/Redness Measure (mm) |          |                  |              |              |              |              |              |              |              |              |                |
| None                     |          | 15 (100)         | 15 (100)     | 13 (87)      | 14 (93)      | 14 (93)      | 14 (93)      | 14 (93)      | 15 (100)     | 15 (100)     | 15 (100)       |
| Mild                     |          | -                | -            | 1 (7)        | -            | -            | -            | -            | -            | -            | 1 (7)         |
| Moderate                 |          | -                | -            | 1 (7)        | -            | 1 (7)        | 1 (7)        | 1 (7)        | -            | -            | 1 (7)         |
| Severe                   |          | -                | -            | -            | 1 (7)        | -            | -            | -            | -            | -            | 1 (7)         |
| Not Reported             |          | -                | -            | -            | -            | -            | -            | -            | -            | -            | -              |

| Induration/Swelling      |          |                  |              |              |              |              |              |              |              |              |                |
| None                     |          | 15 (100)         | 14 (93)      | 14 (93)      | 14 (93)      | 14 (93)      | 14 (93)      | 15 (100)     | 15 (100)     | 15 (100)     | 15 (100)       |
| Mild                     |          | -                | 1 (7)        | 1 (7)        | 1 (7)        | -            | -            | -            | -            | -            | 1 (7)         |
| Moderate                 |          | -                | -            | -            | -            | -            | -            | -            | -            | -            | -              |
TABLE 7B(ii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 100 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7B(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (18-55 years)**

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### TABLE 7B(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number** = Any Dose

**Vaccination Group** – 100 mcg mRNA-1273 (18-55 years) *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
**TABLE 7C(i):**
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

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Vaccination Group – 250 mcg mRNA-1273 (18-55 years)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
## TABLE 7C(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

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### Vaccination Group – 250 mcg mRNA-1273 (18-55 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7C(ii):
**Summary of Local Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Dose 2**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 7C(ii):

**Summary of Local Solicited Events by Days Post Treatment and Vaccination Group**

**Dose Number = Dose 2**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)** (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

a The data for Day 7 and Day 8 following the second vaccination for 2 subjects in Cohort 3 was entered after the time of data cutoff; there were no graded events entered for these 2 subjects for this day.

b Data for Day 8 following the second vaccination for 1 subject in Cohort 3 was confirmed as not available by the site.
### TABLE 7C(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)**

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### TABLE 7C(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 250 mcg mRNA-1273 (18-55 years)** (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7D(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1

Vaccination Group – 25 mcg mRNA-1273 (56-70 years)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 7D(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (56-70 years) *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.  
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7D(ii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 25 mcg mRNA-1273 (56-70 years)

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**TABLE 7D(ii):**

Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

Dose Number = Dose 2

Vaccination Group – 25 mcg mRNA-1273 (56-70 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
**TABLE 7D(iii):**
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (56-70 years)**

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### TABLE 7D(iii):

Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 25 mcg mRNA-1273 (56-70 years)** (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7E(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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Data Cutoff Date: 25MAY2020
Report Date: 02JUN2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
**TABLE 7E(i):**

Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

Dose Number = Dose 1

Vaccination Group – 100 mcg mRNA-1273 (56-70 years) (*continued*)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7E(ii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 2**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

*PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES*
**TABLE 7E(ii):**
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 2
Vaccination Group – 100 mcg mRNA-1273 (56-70 years) *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7E(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Any Dose**

**Vaccination Group – 100 mcg mRNA-1273 (56-70 years)**

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TABLE 7E(iii):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
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Vaccination Group – 100 mcg mRNA-1273 (56-70 years) *(continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
## TABLE 7F(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 25 mcg mRNA-1273 (≥71 years)**

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### TABLE 7F(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 25 mcg mRNA-1273 (≥71 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7G(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group

**Dose Number = Dose 1**

**Vaccination Group – 100 mcg mRNA-1273 (≥71 years)**

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# TABLE 7G(i):
Summary of Local Solicited Events by Days Post Treatment and Vaccination Group
Dose Number = Dose 1
Vaccination Group – 100 mcg mRNA-1273 (≥71 years) (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7H(i):
Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
### TABLE 7H(i):
Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
TABLE 7H(ii):
Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Dose 2

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*Percentages may not sum to 100 due to rounding.
### TABLE 7H(ii):
**Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:**
*Dose Number = Dose 2 (continued)*

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Severity is the maximum severity reported post dosing for each subject for each day.

*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.

a The data for Day 7 and Day 8 following the second vaccination for 2 subjects in Cohort 3 was entered after the time of data cutoff; there were no graded events entered for these 2 subjects for these days.

b Data for Day 8 following the second vaccination for 1 subject in Cohort 3 was confirmed as not available by the site.
TABLE 7H(iii):
Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Any Dose

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
**TABLE 7H(iii):**
Summary of Local Solicited Events for All Vaccination Groups by Day 18-55 Years of Age:
Dose Number = Any Dose (continued)

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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
TABLE 71(i):
Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020

PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES
### TABLE 71(i):
**Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:**
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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7I(ii):
Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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TABLE 7I(ii):
Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7I(iii):
Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
Dose Number = Any Dose

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TABLE 7I(iii):
Summary of Local Solicited Events for All Vaccination Groups by Day 56-70 Years of Age:
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Severity is the maximum severity reported post dosing for each subject for each day.
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
### TABLE 7J(i):
Summary of Local Solicited Events for All Vaccination Groups by Day ≥71 years of Age:
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Summary of Local Solicited Events for All Vaccination Groups by Day ≥71 years of Age:  
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Severity is the maximum severity reported post dosing for each subject for each day.  
*Indicates how many subjects had “None”, “Mild”, “Moderate”, “Severe”, or “Not Reported” as their maximum severity for any day. A subject may be counted in more than one of these categories.
TABLE 8A:  
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter

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**TABLE 8A:**
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter  
(continued)

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## TABLE 8A:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter (continued)

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### TABLE 8A:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
### TABLE 8B: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – White Blood Cells

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<td>(Day -42 to -1)</td>
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PRIVILEGED AND CONFIDENTIAL COMMUNICATION
PREPARED BY EMMES

Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
TABLE 8B:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
White Blood Cells (continued)

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### TABLE 8B:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
White Blood Cells (continued)

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Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – White Blood Cells (continued)

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## TABLE 8B:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
White Blood Cells (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
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## TABLE 8C:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Hemoglobin (continued)

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### TABLE 8C:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Hemoglobin (continued)

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TABLE 8C:  
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Hemoglobin (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
TABLE 8D:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets

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### TABLE 8D:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets (continued)

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### TABLE 8D:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
## TABLE 8D:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets (continued)

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### TABLE 8D:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
### TABLE 8E:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Prothrombin Time

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Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –  
Prothrombin Time (continued)

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TABLE 8E:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Prothrombin Time (continued)

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TABLE 8E:  
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Prothrombin Time (continued)

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TABLE 8E:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Prothrombin Time (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
### TABLE 8F:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Partial Thromboplastin Time

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### TABLE 8F:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Partial Thromboplastin Time (continued)

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TABLE 8F:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Partial Thromboplastin Time (continued)

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### TABLE 8F:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Partial Thromboplastin Time (continued)

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TABLE 8F:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Partial Thromboplastin Time (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unschedule d assessments.
N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
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**TABLE 8G:**
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Any Chemistry Parameter (continued)

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### TABLE 8G: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Any Chemistry Parameter (continued)

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## TABLE 8G:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Any Chemistry Parameter (continued)

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### TABLE 8G:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Any Chemistry Parameter (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
## TABLE 8H:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Creatinine

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### TABLE 8H:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Creatinine (continued)

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Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Creatinine (continued)

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TABLE 8H: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Creatinine (continued)

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TABLE 8H:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Serum Creatinine (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
**TABLE 8I:**
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Alanine Aminotransferase

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### TABLE 8I:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Alanine Aminotransferase (continued)

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### TABLE 8I:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Alanine Aminotransferase (continued)

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N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
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TABLE 8I: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Aspartate Aminotransferase (continued)

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*PRIVILEGED AND CONFIDENTIAL COMMUNICATION*  
*PREPARED BY EMMES*
## TABLE 8I:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Aspartate Aminotransferase *(continued)*

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# TABLE 8I:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Aspartate Aminotransferase (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
## TABLE 8J:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Alkaline Phosphatase

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### TABLE 8J:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Alkaline Phosphatase (continued)

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TABLE 8J:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Alkaline Phosphatase (continued)

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## TABLE 8J:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Alkaline Phosphatase (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
### TABLE 8K:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Total Bilirubin

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### TABLE 8K:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Total Bilirubin (continued)

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**Day 8** (Days 7 to 9)

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## TABLE 8K:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –
Total Bilirubin (continued)

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### TABLE 8K:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Total Bilirubin (continued)

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TABLE 8K: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Total Bilirubin (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
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Laboratory Results by Parameter, Severity, and Study Day
Serum Lipase

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# TABLE 8L:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Lipase (continued)

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**Day 8**
(Days 7 to 9)

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TABLE 8L:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Lipase (continued)

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<th>Severe/ Grade 3</th>
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### TABLE 8L:
Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Serum Lipase (continued)

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Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.
FIGURE 5A:
Clinical Laboratory Results by Severity and Vaccination Group 18-55 Years of Age
FIGURE 5B:
Clinical Laboratory Results by Severity and Vaccination Group 56-70 Years of Age
FIGURE 5C:
Clinical Laboratory Results by Severity and Vaccination Group ≥71 Years of Age

-309-
### TABLE 9A:
Distribution of Protocol Deviations by Category, Type, and Vaccination Group 18-55 Years of Age

<table>
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<tr>
<th>Category</th>
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<th>100 mcg mRNA -1273 (N=15)</th>
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<td>#of Subj.</td>
<td>#of Dev.</td>
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<td>Out of window visit</td>
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<tr>
<td>Protocol procedure/assessment</td>
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<td></td>
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<td>Other: non-required lab tests performed</td>
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<td>1</td>
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<td>Other: v4 safety labs collected out of window</td>
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<td>Treatment administration schedule</td>
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Distribution of Protocol Deviations by Category, Type, and Vaccination Group 56-70 Years of Age

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<tr>
<td>Protocol procedure/assessment</td>
<td>Other: breach of confidentiality</td>
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<td></td>
<td>Other: non-required lab tests performed</td>
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<td></td>
<td>Other: v4 safety labs collected out of window</td>
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TABLE 9C:
Distribution of Protocol Deviations by Category, Type, and Vaccination Group ≥ 71 Years of Age

No protocol deviations have been reported.