DAY 119 CLINICAL STUDY REPORT

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

PROTOCOL NUMBER 20-0003

Name of Test Product:	mRNA-1273
Indication:	COVID-19
ClinicalTrials.gov Identifier:	NCT04283461
Sponsor:	Division of Microbiology and Infectious Diseases (DMID) National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH)/Department of Health and Services (DHHS) 5601 Fishers Lane Rockville, MD 20892-9826
Sponsor Signatory:	P. Chris Roberts, PhD Chief, Respiratory Pathogens Clinical Research Section Respiratory Diseases Branch DMID NIAID/NIH/DHHS Telephone: +1-240-669-5053
Drug Development Phase:	1
Study Initiation Date:	First participant first visit: 16 March 2020
Analysis Data Cutoff Date:	07 October 2020 (data freeze date)
Principal Investigator:	Lisa A. Jackson, MD, MPH Kaiser Permanente Washington Health Research Institute 1730 Minor Avenue, Suite 1600 Seattle, WA 98101
Date of Day 119 Report:	31 March 2021

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

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Synopsis

Title of Study: Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults (ClinicalTrials.gov Identifier: NCT04283461)

Investigator: Lisa A. Jackson

Study Centers: A total of 3 study sites (one of which had a satellite site) in the United States enrolled at least 1 participant in the study.

Publications:

Anderson EJ, Rouphael NG, Widge AT, Jackson LA, Roberts PC, Makhene M, et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. N Engl J Med. 2020;383(25):2427-38.

Jackson LA, Anderson EJ, Rouphael NG, Roberts PC, Makhene M, Coler RN, et al. An mRNA vaccine against SARS-CoV-2 - preliminary report. N Engl J Med. 2020;383(20):1920-31.

Widge AT, Rouphael NG, Jackson LA, Anderson EJ, Roberts PC, Makhene M, et al. Durability of responses after SARS-CoV-2 mRNA-1273 vaccination. N Engl J Med. 2021;384(1):80-82.

Study Period: 16 March 2020 (first participant first visit) to 07 October 2020 (data freeze date for this Day 119 clinical study report)

Drug Development Phase: 1

Background and Rationale: In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus (CoV) RNA was quickly identified in some of these first patients. This novel CoV was originally referred to as 2019-nCoV but was subsequently named SARS-CoV-2 (because of its similarity to the severe acute respiratory syndrome [SARS] CoV [SARS-CoV]). On March 11, 2020 the World Health Organization (WHO) declared CoV disease 2019 (COVID-19) a pandemic.

Global efforts to evaluate novel antivirals and therapeutic strategies to treat SARS-CoV-2 severe infections have intensified, but no proven therapeutic currently exists. Therefore, there is an urgent public health need for rapid development of novel interventions. Furthermore, since older adults are at higher risk for severe illness from COVID-19, it is important to rapidly assess clinical safety of novel vaccines in this vulnerable population as early as possible.

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ModernaTX, Inc. has developed a rapid-response proprietary messenger RNA (mRNA)-based vaccine platform. The platform is based on the principle and observations that cells can take up mRNA, translate it, and then express protein viral antigen(s) on the cell surface. ModernaTX, Inc. has used its mRNA-based platform to develop mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine against SARS-CoV-2. mRNA-1273 encodes the full-length spike (S) protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein into a prefusion conformation (S-2P).

The aim of this Phase I clinical study was to evaluate the safety, reactogenicity, and immunogenicity of ModernaTX's mRNA-1273, administered as 2 doses 28 days apart, in healthy adults across the age spectrum (≥ 18 years of age). The study included older adults (56 to 70 years or ≥ 71 years), because this population is at increased risk of severe illness from COVID-19.

This clinical study report (CSR) provides the interim analysis of safety and immunogenicity data through the data cutoff date of 07 October 2020 (data freeze date) and includes data through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10, 11, and 12.

Objectives and Endpoints:

Objectives	Endpoints
Primary	
• To evaluate the safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart, across 5 dosages in healthy adults	• Frequency and grade of each solicited local and systemic reactogenicity AE during a 7-day follow-up period post each vaccination • Frequency and grade of any unsolicited AEs during the 28-day follow-up period post each vaccination • Frequency of SAEs, NOCMCs, and MAAEs from Day 1 to Day 394
Secondary	
• To evaluate the immunogenicity as measured by IgG ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at Day 57	• GMT of antibody at Day 57 • Percentage of participants who seroconverted, defined as a 4-fold change in antibody titer from baseline • The GMFR in IgG titer from baseline

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Objectives	Endpoints
Exploratory	
• To evaluate the immunogenicity as measured by IgG ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at all time points, other than Day 57	• GMT of antibody at each time point • Percentage of participants who seroconverted at each time point • The GMFR in IgG titer from baseline for each post-vaccination time point
• To evaluate the immunogenicity as measured by IgM and IgA ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT at each time point • Percentage of participants who seroconverted at each time point • The GMFR in IgM and IgA titer from baseline at each post-vaccination time point
• To evaluate the immunogenicity as measured by pseudovirus neutralization following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT of nAb at each time point • Percentage of participants who seroconverted, defined as a 4-fold change in nAb titer from baseline at each time point • The GMFR nAb titer from baseline at each post-vaccination time point
• To evaluate the immunogenicity as measured by live wild-type SARS-CoV-2 neutralization following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT of nAb at each time point • Percentage of participants who seroconverted, defined as a 4-fold change in nAb titer from baseline at each time point • The GMFR in nAb titer from baseline at each post-vaccination time point
• To assess, in at least a subset of samples, the SARS-CoV-2 S protein-specific T-cell responses	• Magnitude, phenotype, and percentage of cytokine-producing S protein-specific T cells, as measured by flow cytometry at different time points post vaccination relative to baseline

Abbreviations: AE = adverse event; ELISA = enzyme-linked immunosorbent assay; GMFR = geometric mean fold rise; GMT = geometric mean titer; IgA = immunoglobulin A; IgG = immunoglobulin G; IgM = immunoglobulin M; MAAE = medically attended adverse event; nAb = neutralizing antibody; NOCMC = new onset of chronic medical condition; S = spike; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Methodology:

This was a Phase 1, open-label, dose-ranging study in males and nonpregnant females, at least 18 years of age, who were in good health and met all eligibility criteria. This clinical study was designed to assess the safety, reactogenicity, and immunogenicity of mRNA-1273 manufactured by ModernaTX. mRNA-1273 is a novel LNP-encapsulated mRNA-based vaccine that encodes a full-length, prefusion stabilized S protein of SARS-CoV-2.

Up to 155 participants were planned to be enrolled in up to 13 cohorts. Participants received an intramuscular (IM) injection (0.5 mL) of mRNA-1273 on Days 1 and 29 in the deltoid

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muscle of the same arm. Participants were observed at the study site for at least 60 minutes after each dose of study vaccine. The injection site was examined immediately prior to each study vaccine administration. Participants are being followed through 12 months after the second vaccination (Day 394). This CSR provides the interim analysis of safety and immunogenicity data through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10, 11, and 12; no participants were enrolled in Cohorts 6, 9, and 13.

Planned Study Cohorts

Cohort	Stratum (age in years)	mRNA-1273 Dose (µg) on Day 1 and Day 29
1	18 to 55	25
2	18 to 55	100
3	18 to 55	250
4	56 to 70	25
5	56 to 70	100
6[a]	56 to 70	250[a]
7	≥ 71	25
8	≥ 71	100
9[a]	≥ 71	250[a]
10	18 to 55	50
11	56 to 70	50
12	≥ 71	50
13[b]	18 to 55	10[b]

[a] Based on review of available interim safety and immunogenicity data, dosing at the 250 µg-dose level was deferred after Cohort 3 (18 to 55 years, n = 15) and prior to enrollment in Cohorts 6 (56 to 70 years, n = 10) and 9 (≥ 71 years, n = 10) to explore lower dosages. Subsequently, a decision was made not to enroll these groups.

[b] Based on review of available interim immunogenicity data, Cohort 13 (10 µg, 18 to 55 years, n=15) will not be enrolled.

Follow-up visits occurred at 1, 2, and 4 weeks post each vaccination (Days 8, 15, 29, 36, 43, and 57) and at 3 months post second vaccination (Day 119). Additional follow-up visits will occur at 6 and 12 months after the second injection (Days 209 and 394). To determine safety signals, enrollment proceeded in a staged fashion for Cohorts 1 through 8 (excluding Cohort 6), with enrollment of 4 sentinel participants each in Cohorts 1, 2, and 3.

Based on review of available interim safety and immunogenicity data, Cohorts 6 and 9 (250 µg; 56 to 70 years of age and ≥ 71 years of age, respectively) and Cohort 13 (10 µg; 18 to 55 years of age) will not be enrolled.

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Safety Assessment:

The primary endpoint in this study was evaluation of the safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart. The safety assessments included monitoring and recording the frequency and grade of solicited local and systemic adverse events (AEs) and unsolicited AEs, the frequency of serious adverse events (SAEs) and AEs of special interest (AESIs; medically attended AEs [MAAEs] and new onset of chronic medical conditions [NOCMCs]), as well as clinical laboratory evaluations, vital sign measurements, and physical examinations.

Reactogenicity was measured by the occurrence of solicited local (injection site) and systemic AEs from the time of each vaccination through 7 days post each vaccination using a memory aid. Additional safety and reactogenicity data were solicited via telephone calls to participants at 1 and 2 days post each vaccination (Days 2, 3, 30, and 31). For consistency across the mRNA-1273 program, solicited AEs were referred to as solicited adverse reactions (ARs) when summarized in the results.

Unsolicited nonserious AEs were collected from the time of each vaccination through 28 days post each vaccination. Serious AEs, NOCMCs, and MAAEs are being collected through 12 months after the last vaccination (Day 394).

Immunogenicity

The secondary and exploratory immunogenicity assessments included the following:

- Immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA) to the SARS-CoV-2 S protein
- Immunoglobulin M and immunoglobulin A ELISA to the SARS-CoV-2 S protein
- Neutralization assay using a SARS-CoV-2 pseudovirus
- Neutralization assay using a live wild-type SARS-CoV-2

Number of Participants (Planned and Analyzed):

Planned: up to 155 participants

Analyzed: 120 participants

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Diagnosis and Main Criteria for Inclusion and Exclusion:

Inclusion criteria:

A participant must have met all of the following criteria to be eligible to participate in this study:

1. Provided written informed consent prior to initiation of any study procedures.
2. Able to understand and agreed to comply with planned study procedures and was available for all study visits.
3. Agreed to the collection of venous blood per protocol.
4. Male or nonpregnant female, ≥18 years of age at time of enrollment.
5. Body mass index (BMI) 18.0 to 35.0 kg/m^2, inclusive (< 56 years of age), at Screening; BMI 18.0 to 30.0 kg/m^2, inclusive (≥ 56 years of age), at Screening.
6. Women of childbearing potential agreed to use or practiced true abstinence or used at least 1 acceptable primary form of contraception.
7. Women of childbearing potential must have had a negative urine or serum pregnancy test within 24 hours prior to each vaccination.
8. Male participants of childbearing potential: use of condoms to ensure effective contraception with a female partner of childbearing potential from first vaccination until 60 days after the last vaccination.
9. Male participants agreed to refrain from sperm donation from the time of first vaccination until 60 days after the last vaccination
10. In good health.
11. Oral temperature was less than 100.0°F (37.8°C).
12. Pulse no greater than 100 beats per minute.
13. Systolic blood pressure was 85 to 150 mm Hg, inclusive.
14. Clinical screening laboratory evaluations (white blood cells, hemoglobin, platelets, alanine aminotransferase, aspartate aminotransferase, creatinine, alkaline phosphatase, total bilirubin, lipase, prothrombin time, partial thromboplastin time) were within acceptable normal reference ranges at the clinical laboratory being used.
15. Agreed to have samples stored for secondary research.
16. Agreed to adhere to Lifestyle Considerations throughout study duration.

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17. Agreed to refrain from donating blood or plasma during the study (outside of this study).

Exclusion criteria:

A participant who met any of the following criteria was excluded from participation in this study.

1. Positive pregnancy test either at Screening or just prior to each vaccine administration.
2. Female participant who was breastfeeding or planned to breastfeed from the time of the first vaccination through 60 days after the last vaccination.
3. Had any medical disease or condition that, in the opinion of the participating site investigator or appropriate subinvestigator, precluded study participation.
4. Presence of self-reported or medically documented significant medical or psychiatric condition(s).
5. Had an acute illness, as determined by the participating site investigator or appropriate subinvestigator, with or without fever [oral temperature ≥ 38.0°C (100.4°F)] within 72 hours prior to each vaccination.
6. Had a positive test result for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus types 1 or 2 antibodies at Screening.
7. Participated in another investigational study involving any investigational product within 60 days, or 5 half-lives, whichever was longer, before the first vaccine administration.
8. Currently enrolled in or planned to participate in another clinical trial with an investigational agent that was to be received during the study reporting period.
9. Previously participated in an investigational study involving LNPs (a component of the investigational vaccine assessed in this trial).
10. Had a history of hypersensitivity or severe allergic reaction (eg, anaphylaxis, generalized urticaria, angioedema, other significant reaction) to any previous licensed or unlicensed vaccines.
11. Chronic use (more than 14 continuous days) of any medications that may have been associated with impaired immune responsiveness.
12. Anticipated the need for immunosuppressive treatment within the next 6 months.

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13. Received immunoglobulins and/or any blood or blood products within the 4 months before the first vaccine administration or at any time during the study.
14. Had any blood dyscrasias or significant disorder of coagulation.
15. Had any chronic liver disease, including fatty liver.
16. Had a history of alcohol abuse or other recreational drug (excluding cannabis) use within 6 months before the first vaccine administration.
17. Had a positive test result for drugs of abuse at screening or before the first vaccine administration. If cannabis was the only detected drug, inclusion was permitted.
18. Had any abnormality or permanent body art (eg, tattoo) that would interfere with the ability to observe local reactions at the injection site (deltoid region).
19. Received or planned to receive a licensed, live vaccine within 4 weeks before or after each vaccination.
20. Received or planned to receive a licensed, inactivated vaccine within 2 weeks before or after each vaccination.
21. Received any other SARS-CoV-2 or other experimental coronavirus vaccine at any time prior to or during the study.
22. Had close contact of anyone known to have SARS-CoV-2 infection within 30 days prior to vaccine administration.
23. History of COVID-19 diagnosis.
24. On current treatment with investigational agents for prophylaxis of COVID-19.
25. Current use of any prescription or over-the-counter medications within 7 days prior to vaccination, unless approved by the investigator or necessary to manage a chronic condition.
26. Planned to travel outside the United States (continental United States, Hawaii, and Alaska) from enrollment through 28 days after the second vaccination.
27. Resided in a nursing home or other skilled nursing facility or had a requirement for skilled nursing care.
28. Nonambulatory.
29. For participants ≥ 56 years of age, history of chronic smoking within the prior year.
30. For participants ≥ 56 years of age, current smoking or vaping.

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31. For participants ≥ 56 years of age, individuals currently working with high risk of exposure to SARS-CoV-2 (eg, active health care workers with direct patient contact, emergency response personnel).

Test Product, Dose and Mode of Administration, Batch Number: 25 µg, 50 µg, 100 µg, and 250 µg of mRNA-1273 administered as an IM injection (0.5 mL) into the deltoid muscle on a 2-dose injection schedule on Day 1 and Day 29, with a 28-day interval between doses. The second dose of study vaccine was administered preferably in the same arm as the first dose. Lot 8520100101.

Control Product, Dose and Mode of Administration, Batch Number: Not applicable.

Duration of Treatment: Participants received their assigned dose of mRNA-1273 as a 2 vaccination schedule separated by approximately 28 days.

Estimands and Intercurrent Events: Not applicable

Statistical Methods:

Safety:

Solicited AEs: Solicited AEs were graded on a scale of 0 (absent), 1 (mild), 2 (moderate), and 3 (severe). Solicited systemic AEs included fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), arthralgia (captured in the memory aid as joint pain), nausea, feverishness (captured in the memory aid as chills), and fever. Solicited local AEs included pain at injection site, erythema (captured in the memory aid as redness), and induration (captured in the memory aid as swelling/hardness).

For consistency across the mRNA-1273 program, these solicited AEs were referred to as solicited ARs when summarized in the results.

The proportion of participants reporting at least 1 solicited AR was summarized for each solicited AR, any systemic symptom, any local symptom, and any symptoms. The mean, SD, median, minimum, and maximum duration of solicited ARs were summarized. Day of solicited symptom onset and maximum severity on the day of onset were also summarized.

Unsolicited AEs: The proportion of participants reporting at least 1 unsolicited AE was summarized by Medical Dictionary for Regulatory Activities system organ class and preferred term for each dose of study vaccine and over all doses.

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Immunogenicity:

Summaries and analysis of immunogenicity data were presented for the per-protocol population.

Seroconversion was defined as a 4-fold increase in antibody titer over baseline. For the secondary immunogenicity endpoint, seroconversion rates, geometric mean fold rise (GMFR), geometric mean titer (GMT), and Williams mean of the area under the curve (AUC) for SARS-CoV-2 (S-2P and receptor binding domain [RBD]) as measured by IgG ELISA were calculated on Days 1 (GMT only) and 57 by cohort and were summarized graphically. Seroconversion rates, GMFR, GMT, and Williams mean of the AUC were presented with their corresponding 95% confidence interval (CI) estimates (using Student's t-distribution) at each time point.

For SARS-CoV-2–specific binding antibodies, seroconversion rates, GMFR, GMT, and Williams mean of AUC for SARS-CoV-2 (S-2P and RBD) as measured by IgG ELISA were calculated for specified time points by cohort.

The SARS-CoV-2 pseudovirus neutralization assay (PsVNA) and a wild-type SARS-CoV-2 plaque reduction neutralization test (PRNT) were performed using serial dilutions of sera. The serum dilution required to achieve 50% and 80% neutralization (ID_{50} and ID_{80}, respectively) were calculated for PsVNA data using a 5-parameter logistic regression model and were summarized by group using the geometric mean (GM) and 95% CI (using Student's t-distribution). Similarly, for PRNT data, 80% plaque reduction neutralization titer ($PRNT_{80}$) was calculated using a 5-parameter logistic model and was summarized using a GM and 95% CI. The minimum, median, and maximum were also reported.

Similar methods were used to summarize all additional neutralization assays performed (eg, a live-virus focus-reduction neutralization test [FRNT]; and FRNT using mNeonGreen [FRNT-mNG]). Spearman correlation between various neutralization assays were assessed.

The magnitude, phenotype, and percentage of cytokine-producing S protein-specific T cells were summarized at each time point by vaccination group.

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Summary of Results:

The results reported in this CSR include interim analysis of safety and immunogenicity data through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10, 11, and 12.

Participant Disposition: A total of 256 potential participants were screened across all age groups, and 120 participants were enrolled. All participants received the first injection, and 116 participants received the second injection; 4 participants discontinued the vaccine after the first injection (1 participant due to potential COVID-19 exposure and 3 participants due to AEs). No participant discontinued from the study at the time of data cutoff. All participants in Cohorts 10, 11, and 12 completed the planned follow-up visits through Day 57, and all participants in Cohorts 1 through 5, 7, and 8 completed the planned follow-up through Day 119.

Safety Results:

Note: For consistency across the mRNA-1273 program, solicited AEs were referred to as solicited ARs when summarized in the results.

- Overall, mRNA-1273 demonstrated an acceptable safety profile.
- No serious AEs or AEs leading to study discontinuation were noted.
- Most of the solicited ARs were mild or moderate. In the 18 to 55 years of age group, severe solicited ARs predominantly occurred at the highest dose (250 µg): 4 participants in the 250 µg versus 1 participant each in the 50 µg and 100 µg vaccination groups. Additionally, severe solicited ARs were reported in 1 participant each in the 25 µg and 50 µg vaccination groups (age group: 56 to 70 years) and 1 participant in the 100 µg vaccination group (age group: ≥ 71 years).
- The most commonly reported solicited systemic ARs after any dose across all age groups were fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), and feverishness (captured in the memory aid as chills). The incidence of solicited systemic ARs was higher after the second injection than after the first injection. Overall, fatigue and headache were the most commonly reported solicited systemic ARs after the first injection; fatigue, headache, myalgia, and feverishness were the most commonly reported solicited

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systemic ARs after the second injection. Notably, in the 18 to 55 years of age group, the incidence of arthralgia, feverishness, headache, myalgia, and nausea increased by more than 2-fold after the second injection compared with the incidence after the first injection, and no participant reported fever after the first injection, but 15 (26%) participants reported fever after the second injection. In all age groups, severe solicited systemic ARs occurred only after the second injection.

- Overall, injection site pain was the most commonly reported solicited local AR. The incidence of the solicited local ARs was similar after the first injection and after the second injection.

- Most of solicited ARs had an onset within 2 days after vaccination, and the median durations of solicited ARs were 1 to 2 days. Notably, all severe solicited ARs resolved within 1 to 2 days.

- The incidence of unsolicited AEs was similar among vaccination groups across all age groups. Most unsolicited AEs were mild or moderate in severity.

- All unsolicited AEs related to mRNA-1273 were mild or moderate in severity, except for 2 severe AEs (dizziness and syncope, both occurring on Day 1 after the second injection) in 1 participant in the 18 to 55 years of age group (250 µg vaccination group). All AEs related to mRNA-1273 resolved.

- Adverse events leading to treatment discontinuation were reported in 3 participants. Of these, 1 mild AE of urticaria (25 µg vaccination group, age group: 18 to 55 years) was related to mRNA-1273.

- A total of 33 MAAEs were reported in 24 participants. All MAAEs were considered not related to mRNA-1273, except 1 MAAE (moderate abdominal discomfort) in 1 participant in the 18 to 55 years of age group (250 µg vaccination group). One AE (moderate bone density decreased) in one participant in the 56 to 70 years of age group (25 µg vaccination group) was captured as both an MAAE and NOCMC and was not related to mRNA-1273.

- Overall, no notable trends were observed in the hematology and chemistry laboratory test results for any vaccination group, and no trends were observed among dose level and the severity of events.

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- One severe abnormal laboratory result (serum lipase; 18 to 55 years of age group, 250 µg vaccination group) was considered related to mRNA-1273.

- No notable trends were observed in vital sign results and physical examination findings for any age group or vaccination group, and no trend was observed among dose levels and the severity of events.

- Based on the safety findings that a higher incidence of severe solicited ARs was noted in the 250 µg group, the only participant reporting severe unsolicited AEs related to mRNA-1273 received 250 µg of mRNA-1273, and the only severe clinically meaningful laboratory abnormality (increased serum lipase) related to mRNA-1273 was noted in the 250 µg group; the 100 µg, 50 µg, and 25 µg dose levels can be considered to have a more acceptable safety profile than the 250 µg dose level. This was the rationale for not continuing to evaluate the 250 µg dose in the older age cohorts.

Immunogenicity:

mRNA-1273 administered as 2 doses separated by 28 days induced robust humoral and cellular immune responses. In general, dose-dependent increases in binding and neutralizing antibody responses were detected across age groups. Binding and neutralizing antibody responses among all age groups for the 100 µg vaccination dose persisted through Day 119 at levels that declined modestly relative to Day 57 but remained similar to or higher than responses in a convalescent sera panel. mRNA-1273 elicited a strong Th1-biased CD4 T cell response.

- S-2P IgG ELISA Endpoint

    - The S-2P ELISA results demonstrated a robust antibody response after each dose. The S-2P ELISA GMT values were generally numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups across all age groups. The S-2P ELISA GMT values in the 250 µg vaccination group were numerically higher than those in the 100 µg vaccination group in the 18 to 55 years of age group.

    - The S-2P ELISA GMT values for Day 43 and Day 57 were numerically higher than those for the convalescent sera control group across all age groups and dosage levels.

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- Seroconversion (4-fold rise in endpoint titer from baseline) to S-2P was observed by Day 15 in all participants in the 18-55 years of age groups, by Day 29 in all participants in the 56-70 years of age groups, and by Day 36 in all participants in the ≥71 years of age group.

- For the 100 µg and 250 µg mRNA-1273 doses, the S-2P ELISA GMT values at Day 119 were numerically higher than that for the convalescent sera control group.

- RBD IgG ELISA Endpoint

  - The RBD ELISA results demonstrated a robust antibody response after each dose.

  - The RBD ELISA GMT values were numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups in the 56 to 70 and ≥ 71 years of age groups.

  - For all age groups and mRNA-1273 dose levels, the RBD ELISA GMT values for Day 36 and beyond exceeded the median GMT values for the convalescent sera control group.

  - The RBD ELISA GMFR results consistently showed robust responses across all age groups, and the seroconversion criteria were met at the majority of postbaseline visits.

- Pseudovirus Neutralization ID_{50} and ID_{80}

  - The PsVNA GM titers (ID_{50} and ID_{80}) for the 614D variant were undetectable prior to the first injection, marginally increased after the first injection, and substantially increased after the second injection.

  - The PsVNA GM titers (ID_{50} and ID_{80}) after 2 injections were similar at Day 57 among the 50 µg, 100 µg, and 250 µg vaccination groups in the 18 to 55 years of age group. In both the 56 to 70 and ≥ 71 years of age groups, the PsVNA GM titers (ID_{50} and ID_{80}) after 2 injections numerically were higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups.

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- The GM titers for the 100 µg mRNA-1273 vaccination group from Day 36 through Day 119 were similar to (≥ 71 years of age group) or exceeded (18 to 55 and 56 to 70 years of age groups) the GM titers from the convalescent sera control group.

- Robust neutralizing antibody responses to the 614G variant were also observed at Day 43 for the 100 µg vaccination group regardless of age.

- $PRNT_{80}$ GMT

  - The $PRNT_{80}$ GM values were undetectable prior to the first injection but were readily detectable and increased substantially after the second injection.

- FRNT-mNG

  - The FRNT-mNG GM neutralizing titers (ID_{50} and ID_{80}) were undetectable prior to the first injection, marginally increased after the first injection, and substantially increased after the second injection on Day 43 for all age groups and mRNA-1273 dose groups.

- Correlations were found within and between the values from binding antibody assays and neutralizing activity. The correlation between live-virus and pseudovirus neutralization with S-2P and RBD ELISA provides orthogonal support for each assay in characterizing the humoral response induced by mRNA-1273.

The T-cell response data supported the cellular immunity profile for mRNA-1273 with the following observations:

- The 25 and 100 µg doses elicited CD4 T-cell responses that, upon stimulation by S-specific peptide pools, were strongly biased toward the expression of Th1 cytokines (tumor necrosis factor α > interleukin 2 > interferon γ) with minimal Th2 cytokine expression (interleukin 4 and interleukin 13). The responses to the 100 µg dose were numerically higher than those for the 25 µg dose across all age groups.

- The CD8 T-cell responses were low to absent across the age stratum in the 25 µg and 100 µg vaccination groups.

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Conclusions:

mRNA-1273, administered as 2 doses 28 days apart, was safe and immunogenic in healthy adult participants aged ≥ 18 years. After mRNA-1273 administration, fatigue, headache, myalgia, feverishness, and injection site pain were the most commonly reported solicited systemic and local ARs, with higher incidence noted after the second injection than after the first injection for the solicited systemic ARs. Most of the solicited ARs were mild or moderate; severe solicited ARs predominantly occurred at the highest dose (250 µg). The ARs lasted a median of 2 days or less. In general, ARs were less severe and less commonly reported in older than in younger adults. All unsolicited AEs related to mRNA-1273 were mild or moderate in severity, except for 2 severe AEs reported in 1 participant in the 250 µg vaccination group (18 to 55 years of age group).

mRNA-1273 induced robust binding antibody responses (S-2P and RBD specific) after 2 injections. Notably, 100 µg of mRNA-1273 resulted in numerically higher S-2P specific binding titers than 25 µg and 50 µg of mRNA-1273 in all age groups and higher RBD–specific binding titers in participants aged > 55 years. Two injections of mRNA-1273 induced robust neutralizing antibody responses. The neutralizing antibody response increased marginally after the first injection but increased substantially after the second injection. The neutralizing antibody response (assessed by a pseudovirus neutralization assay) at the 100 µg mRNA-1273 dose level was similar to that at the 250 µg mRNA-1273 dose level in the 18 to 55 years of age group and numerically higher than that observed at the 25 µg and 50 µg mRNA-1273 dose levels in the older age groups. The neutralizing antibody response at the 100 µg dose was similar across all age groups. mRNA-1273 also elicited CD4 T-cell responses that, upon stimulation by S-specific peptide pools, were strongly biased toward the expression of Th1 cytokines.

Based on the results of safety and immunogenicity at data cutoff, the 100 µg dose provides promising immunogenicity results in adults of all ages with an acceptable safety profile and was the dose selected for further evaluation in the Phase 3 clinical study.

Date and Version of This Report: 31 March 2021

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List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AR	adverse reaction
AST	aspartate aminotransferase
AUC	area under the curve
BMI	body mass index
BP	blood pressure
CFR	Code of Federal Regulations
CI	confidence interval
CMP	clinical monitoring plan
CMV	cytomegalovirus
CoV	coronavirus
COVID-19	coronavirus disease 2019
CQMP	Clinical Quality Management Plan
Cr	creatinine
CROMS	Clinical Research Operations and Management Support
CSR	clinical study report
DCF	data collection form
DMID	Division of Microbiology and Infectious Diseases
DSPC	1,2-distearoyl-sn-glycero-3-phosphocholine
ELISA	enzyme-linked immunosorbent assay
ERD	enhanced respiratory disease
FDA	Food and Drug Administration
FRNT	focus-reduction neutralization test
FRNT-mNG	focus-reduction neutralization test using mNeonGreen
GCP	Good Clinical Practice
GM	geometric mean
GMFR	geometric mean fold rise
GMT	geometric mean titer
Hgb	hemoglobin
HIV	human immunodeficiency virus

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Abbreviation	Definition
hMPV	human metapneumovirus
ICF	informed consent form
ICH	International Council for Harmonisation
ID_{50}	serum dilution required to achieve 50% neutralization
ID_{80}	serum dilution required to achieve 80% neutralization
IgA	immunoglobulin A
IgG	immunoglobulin G
IgM	immunoglobulin M
IM	intramuscular
IRB	institutional review board
LNP	lipid nanoparticle
MAAE	medically attended adverse event
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified intent to treat
MOP	manual of procedures
mRNA	messenger RNA
NaCl	sodium chloride
NHP	nonhuman primate
NOCMC	new onset of chronic medical condition
OHRP	Office of Human Research Protection
PBMC	peripheral blood mononuclear cell
PEG2000-DMG	1 monomethoxypolyethyleneglycol-2,3-dimyristylglycerol polyethylene glycol
PIV3	parainfluenza virus type 3
PLT	platelet
PP	per protocol
PRNT	plaque reduction neutralization test
$PRNT_{80}$	80% plaque reduction neutralization titer
PsVNA	pseudovirus neutralization assay
PT	preferred term
RBD	receptor binding domain
S-2P	spike protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein into a prefusion conformation
SAE	serious adverse event

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Abbreviation	Definition
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SDCC	Statistical and Data Coordinating Center
SM-102	heptadecane-9-yl 8 ((2 hydroxyethyl)(6 oxo 6-(undecyloxy) hexyl)amino) octanoate
SMC	safety monitoring committee
SOC	system organ class
T. Bili	total bilirubin
Th1	T-helper 1
Th2	T-helper 2
USP	United States Pharmacopeia
VRC	Vaccine Research Center
WBC	white blood cell
WHO	World Health Organization

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1 Introduction

In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus (CoV) RNA was quickly identified in some of these first patients. This novel CoV was originally referred to as 2019-nCoV but was subsequently named SARS-CoV-2 (because of its similarity to the severe acute respiratory syndrome [SARS] CoV [SARS-CoV]). It has 89% nucleotide identity with bat SARS-like-CoVZXC21 and 82% with that of human SARS-CoV (Chan et al 2020). The disease caused by SARS-CoV-2 is called CoV disease 2019 (COVID-19). On 30 Jan 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the COVID-19 outbreak a Public Health Emergency of International Concern. On 31 Jan 2020, the US Department of Health and Human Services declared a public health emergency in the United States. On 11 Mar 2020, the WHO declared COVID-19 a pandemic.

Global efforts to evaluate novel antivirals and therapeutic strategies to treat SARS-CoV-2 severe infections have intensified, but no proven therapeutic currently exists. There is currently no vaccine against the SARS-CoV-2 virus approved in the United States. Therefore, there is an urgent public health need for rapid development of novel interventions. Furthermore, since older adults are at higher risk for severe illness from COVID-19, it is important to rapidly assess clinical safety of novel vaccines in this vulnerable population as early as possible.

ModernaTX, Inc. has developed a rapid-response proprietary messenger RNA (mRNA)-based vaccine platform. The platform is based on the principle and observations that cells can take up mRNA, translate it, and then express protein viral antigen(s) on the cell surface. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is nonreplicating, and is expressed transiently. mRNA vaccines have been used to induce immune responses against infectious pathogens such as cytomegalovirus (CMV) (NCT03382405), human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) (NCT03392389), and influenza virus (NCT03076385 and NCT03345043).

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

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

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

At the time of initiation of this study, there were 8 clinical studies initiated across ModernaTX's infectious disease vaccine platform, with over 1,000 participants receiving at least 1 dose of an mRNA vaccine. mRNA vaccines with SM-102-containing lipid formulations were being evaluated in 3 indications: prophylactic protection against CMV (NCT03382405), hMPV/PIV3 (NCT03392389), and Zika virus (NCT04064905). As of 06 Jan 2020, approximately 365 participants were dosed with either an SM-102-containing lipid vaccine or placebo (doses ranging from 10 to 300 μg) across these three Phase 1 studies. Of the 365 participants dosed, 264 participants experienced at least 1 solicited adverse reaction (AR). The most common solicited events were pain (28% of total events reported), headache (15%), fatigue (15%), myalgia (13%), arthralgia (9%), nausea (7%), chills (6%), fever (4%), erythema (2%), and swelling (2%). The majority of the events were of grade 1 to 2, with approximately 9% being reported as grade 3. The most common grade 3 events were pain, myalgia, fatigue, headache, and chills. Grade 3 events were typically recorded on Day 1 or Day 2 following vaccination, with most occurring on Day 2 and resolving by Day 6. There were no related serious adverse events (SAEs) reported in the three Phase 1 vaccine studies.

mRNA-1273 is also currently being evaluated in a Phase 2a, randomized, observer-blind, placebo-controlled, dose-finding study in adults aged 18 years and older and in a Phase 3, randomized, observer-blind, placebo-controlled study in adults aged 18 years and older.

This Phase 1 study is sponsored by the Division of Microbiology and Infectious Diseases (DMID). Decisions related to this study were made by the protocol team, which included representatives from the study sites (investigators), the DMID (sponsor), Vaccine Research Center (VRC), and ModernaTX.

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The aim of this Phase I clinical study was to evaluate the safety, reactogenicity, and immunogenicity of ModernaTX's mRNA-1273, administered as 2 doses 28 days apart, in healthy adults across the age spectrum (≥ 18 years of age). The study included older adults (56 to 70 years or ≥ 71 years), because this population is at increased risk of severe illness from COVID-19. The range of doses included in this study were within the range of ModernaTX's previous trials in SM-102–containing mRNA vaccines and allowed for identification of the optimal dose for Phase 2a and Phase 3 studies.

This clinical study report (CSR) provides the interim analysis of safety and immunogenicity data through the data cutoff date of 07 October 2020 (data freeze date) and includes data through Day 119 for Cohorts 1 through 5, 7, and 8 (Table 2) and through Day 57 for Cohorts 10, 11, and 12 (change to planned analysis; Section 4.3); no participants were enrolled in Cohorts 6, 9, and 13. The final analyses will be performed after the final data lock (through Day 394) and a CSR will be completed when all primary safety endpoint data and all secondary immunogenicity endpoint data are available and received by the Statistical and Data Coordinating Center (SDCC). Any available data from the exploratory immunogenicity endpoints may also be included. Remaining exploratory immunogenicity endpoint data may be included in an addendum to the CSR, publication of manuscript(s), or other report(s).

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2 Study Objectives and Endpoints

The study objectives and endpoints are presented in Table 1.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
• To evaluate the safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart, across 5 dosages in healthy adults	• Frequency and grade of each solicited local and systemic reactogenicity AE during a 7-day follow-up period post each vaccination • Frequency and grade of any unsolicited AEs during the 28-day follow-up period post each vaccination • Frequency of SAEs, NOCMCs, and MAAEs from Day 1 to Day 394
Secondary	
• To evaluate the immunogenicity as measured by IgG ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at Day 57	• GMT of antibody at Day 57 • Percentage of participants who seroconverted, defined as a 4-fold change in antibody titer from baseline • The GMFR in IgG titer from baseline
Exploratory	
• To evaluate the immunogenicity as measured by IgG ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at all time points, other than Day 57	• GMT of antibody at each time point • Percentage of participants who seroconverted at each time point • The GMFR in IgG titer from baseline for each post-vaccination time point
• To evaluate the immunogenicity as measured by IgM and IgA ELISA to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT at each time point • Percentage of participants who seroconverted at each time point • The GMFR in IgM and IgA titer from baseline at each post-vaccination time point
• To evaluate the immunogenicity as measured by pseudovirus neutralization following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT of nAb at each time point • Percentage of participants who seroconverted, defined as a 4-fold change in nAb titer from baseline at each time point • The GMFR nAb titer from baseline at each post-vaccination time point
• To evaluate the immunogenicity as measured by live wild-type SARS-CoV-2 neutralization following a 2-dose vaccination schedule of mRNA-1273 given 28 days apart	• GMT of nAb at each time point • Percentage of participants who seroconverted, defined as a 4-fold change in nAb titer from baseline at each time point • The GMFR in nAb titer from baseline at each post-vaccination time point

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Objectives	Endpoints
• To assess, in at least a subset of samples, the SARS-CoV-2 S protein-specific T-cell responses	• Magnitude, phenotype, and percentage of cytokine-producing S protein-specific T cells, as measured by flow cytometry at different time points post vaccination relative to baseline

Abbreviations: AE = adverse event; ELISA = enzyme-linked immunosorbent assay; GMFR = geometric mean fold rise; GMT = geometric mean titer; IgA = immunoglobulin A; IgG = immunoglobulin G; IgM = immunoglobulin M; MAAE = medically attended adverse event; nAb = neutralizing antibody; NOCMC = new onset of chronic medical condition; S = spike; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

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3 Investigational Plan

3.1 Overall Study Design and Plan

This was a Phase 1, open-label, dose-ranging study in males and nonpregnant females, at least 18 years of age, who were in good health and met all eligibility criteria. This clinical study was designed to assess the safety, reactogenicity, and immunogenicity of mRNA-1273 manufactured by ModernaTX. mRNA-1273 is a novel LNP-encapsulated mRNA-based vaccine that encodes a full-length, prefusion stabilized S protein of SARS-CoV-2. Enrollment occurred at 3 study sites in the United States.

Up to 155 participants were planned to be enrolled in up to 13 cohorts (Table 2). Participants received an intramuscular (IM) injection (0.5 mL) of mRNA-1273 on Days 1 and 29 in the deltoid muscle of the same arm. Participants are being followed through 12 months after the second vaccination (Day 394). This CSR provides the interim analysis of safety and immunogenicity data through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10, 11, and 12; no participants were enrolled in Cohorts 6, 9, and 13.

Table 2: Planned Study Cohorts

Cohort	Stratum (age in years)	mRNA-1273 Dose (µg) on Day 1 and Day 29
1	18 to 55	25
2	18 to 55	100
3	18 to 55	250
4	56 to 70	25
5	56 to 70	100
6[a]	56 to 70	250[a]
7	≥ 71	25
8	≥ 71	100
9[a]	≥ 71	250[a]
10	18 to 55	50
11	56 to 70	50
12	≥ 71	50
13[b]	18 to 55	10[b]

[a] Based on review of available interim safety and immunogenicity data, dosing at the 250 µg dose level was deferred after Cohort 3 (18 to 55 years, n = 15) and prior to enrollment in Cohorts 6 (56 to 70 years, n = 10) and 9 (≥ 71 years, n = 10) to explore lower dosages. Subsequently, a decision was made not to enroll these cohorts.

[b] Based on review of available interim immunogenicity data, Cohort 13 (10 µg, 18 to 55 years, n=15) will not be enrolled.

To determine early safety signals for this Phase 1 study, enrollment proceeded in a staged fashion for Cohorts 1 through 8 (excluding Cohort 6), with enrollment of 4 sentinel participants

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each in Cohorts 1, 2, and 3, as detailed in Section 3.6.3. Participants were enrolled simultaneously in Cohorts 10, 11, and 12; there was no staging.

Follow-up visits occurred at 1, 2, and 4 weeks post each vaccination (Days 8, 15, 29, 36, 43, and 57) and at 3 months post second vaccination (Day 119). Reactogenicity was assessed at these visits, and blood was drawn for immunogenicity assays. Additional safety and reactogenicity data were solicited via telephone calls to participants at 1 and 2 days post each vaccination (Days 2, 3, 30, and 31). Additional follow-up visits will occur at 6 and 12 months after the second injection (Days 209 and 394).

Reactogenicity was measured by the occurrence of solicited local (injection site) and systemic adverse events (AEs) from the time of each vaccination through 7 days post each vaccination (for consistency across the mRNA-1273 program, solicited AEs were referred to as solicited ARs when summarized in the results). Unsolicited nonserious AEs were collected from the time of each vaccination through 28 days post each vaccination. Serious AEs, new onset of chronic medical conditions (NOCMCs), and medically attended AEs (MAAEs) are being collected through 12 months after the last vaccination (Day 394).

Clinical safety laboratory evaluations were performed at screening and immediately before each vaccination and at 7 days post each vaccination (Days 1, 8, 29, and 36).

Evaluation of immunogenicity included quantitation of antibodies to the SARS-CoV-2 S protein at multiple time points post vaccination as measured by enzyme-linked immunosorbent assay (ELISA) and pseudovirus and live wild-type virus neutralization assays, and exploratory studies to characterize T-cell responses. Venous blood was also collected at multiple time points post vaccination for the secondary research use of serum, plasma, and peripheral blood mononuclear cells (PBMCs).

To support development of diagnostics, therapeutics, and vaccines, a subset of participants enrolled in Cohorts 2, 3, 5, 10, and 11 have undergone leukapheresis to collect additional samples for secondary research.

Early data reviews by the study team were performed, as detailed in Section 4.1.5. The Schedule of Activities for all participants is presented in 20-0003 Clinical Study Protocol Section 1.2, Table 4 (Appendix 16.1.1).

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3.1.1 Discussion of Study Design

This study was designed as an open-label study, without a placebo arm. Given the small sample size, the use of a placebo group was unlikely to improve understanding of AEs. Additionally, having the study unblinded facilitated the need for rapid review and dissemination of study data for public health reasons.

This was a first-in-human study of mRNA-1273, and preclinical evaluations occurred in parallel with this Phase 1 study. Data from nonclinical immunogenicity, biodistribution, and safety studies have been completed with similar mRNA-based vaccines formulated in SM-102–containing LNPs and were used in support of development of mRNA-1273 for prophylaxis against SARS-CoV-2 infection. In several of ModernaTX's ongoing Phase 1 dose-ranging studies for other vaccine candidates (mRNA-1653, a combination vaccine against hMPV and hPIV3; mRNA-1647 and mRNA-1443, both CMV vaccines; and mRNA-1893 against Zika virus) dosage levels of mRNA between 10 and 300 µg were administered IM as 1-, 2-, or 3-dose vaccination schedules. Immunogenicity and reactogenicity increased in a dose-dependent manner. The dosage levels proposed for this study (10 µg, 25 µg, 50 µg, 100 µg, and 250 µg) were within the range of previous studies.

The target population selected for this study was intended to be reflective of the community at large.

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

3.2.1 Changes in the Conduct of the Study

The original 20-0003 Clinical Study Protocol, dated 14 Feb 2020, was amended 5 times. Table 3 provides a summary of the major changes implemented with Versions 2.0 through Version 5.0. Version 6.0 of the protocol was not included or discussed in this CSR and will be captured in a subsequent CSR for this study. The original protocol and protocol Versions 2.0 through 5.0, including a summary of changes, are provided in Appendix 16.1.1.

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Table 3: Summary of Major Changes Implemented With Each Amendment

Protocol Amendment	Summary of Major Changes
Protocol Version 1.0 (14 Feb 2020)	Original
Amendment 1, Version 2.0 (13 Mar 2020)	• Adjusted visit windows • Added inclusion criterion #16 to require participants refrain from donating blood or plasma (outside of study); formerly an exclusion criterion • Revised exclusion criterion #21 to specify that participants could not have had close contact with anyone known to have SARS-CoV-2 infection within 30 days prior to vaccine administration (revised from 2 weeks) • Deleted exclusion criterion #22 that restricted travel to countries/regions with known widespread community transmission (addressed with revision to exclusion criterion #21) • Revised lifestyle restrictions • Revised dosing and administration instructions • Revised halting and sentinel halting criteria, including revising halting criterion #5, which clarified reference to grade 3 AEs was unsolicited and/or clinical laboratory abnormality and not systemic and/or clinical laboratory abnormality • Revised dosing and redosing criteria • Clarified AESI reporting
Amendment 2, Version 3.0 (30 Mar 2020)	• Refined eligibility criteria • Included cohort > 55 years of age • Included leukapheresis for a subset of participants
Amendment 3, Version 4.0 (20 May 2020)	• Added 10 and 50 µg dosage cohorts and updated the number of cohorts and participants (added and clarified throughout to account for this revision) • Revised timing and added conditions for enrollment of Cohorts 6 and 9 • Added timing and conditions for enrollment of Cohorts 10 though 13 • Updated/included timing of early and Day 57 data reviews for Cohorts 6 and 9 through 13 • Revised cohorts eligible for leukapheresis • Updated inclusion criteria for body mass index and systolic blood pressure • Updated leukapheresis inclusion criteria for cohorts eligible for leukapheresis • Updated exclusion criteria for chronic kidney disease eGFR value, as well as for participants ≥ 56 years of age - history of chronic smoking, current smoking or vaping, and individuals currently working with high risk of exposure to SARS-CoV-2 • Updated/added treatment assignment procedures for Cohorts 6 and 9 though 13

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Protocol Amendment	Summary of Major Changes
Amendment 4, Version 5.0 (04 Dec 2020)	• Updated the number of dosages from 3 to 5 in the primary objective • Removed exploratory objective, endpoints, and supportive text for B cell analyses. B cell analysis was considered as secondary research instead of primary research • Clarified that for interim safety analyses cumulative AE data were provided to the SMC after all participants in all cohorts completed Day 57 • Updated interim immunogenicity and safety review to state that additional separate interim analyses may be conducted as needed

Abbreviations: AE=adverse event; AESI=adverse event of special interest; eGFR=estimated glomerular filtration rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SMC=safety monitoring committee.

3.3 Investigators and Study Administrative Structure

This study was sponsored by the DMID. Decisions related to this study were made by the protocol team, which included representatives from the study sites (investigators), the DMID (sponsor), VRC, and ModernaTX.

A total of 3 study sites (one of which had a satellite site) in the United States enrolled at least 1 participant in the study. The first participant's first visit for this study was 16 March 2020. This study is ongoing; this interim analysis includes data through Day 119 (Cohorts 1 through 5, 7, and 8) or Day 57 (Cohorts 10, 11, and 12).

The sponsor, DMID (Bethesda, MD), was responsible for project management. The DMID Clinical Research Operations and Management Support (CROMS) contractor, ICON Clinical Research (North Wales, PA), was responsible for study site management. ModernaTX (Norwood, MA) manufactured mRNA-1273 study vaccine. The DMID, via the DMID Clinical Materials Services contract, Fisher BioServices (Germantown, MD), distributed the study vaccine to the study sites. The DMID CROMS contractor, Technical Resources International, Inc. (Bethesda, MD), was responsible for safety monitoring and pharmacovigilance. The Emmes Company, LLC SDCC (Rockville, MD) was responsible for data management, biostatistics, and programming. PPD (Wilmington, NC) was responsible for medical writing and publishing.

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Clinical Laboratories:

- Quest Diagnostics
  1737 Airport Way, Suite 200
  Seattle, WA 98134
- CHoA Multispecialty, LLC
  2015 Uppergate Drive NE
  Atlanta, GA 30322
- Quest Laboratory
  1777 Montreal Circle
  Tucker, GA 30084
- The Hope Clinic of Emory University
  500 Irvin Court, Suite 200
  Decatur, GA 30030
- National Institutes of Health, Clinical Center
  Department of Laboratory Medicine
  10 Center Drive-MSC 1508, Building 10,
  Room 2C306
  Bethesda, MD 20892-1808

Immunogenicity Laboratories:

- Immunoglobulin G (IgG) ELISA, pseudovirus neutralization assay (PsVNA), intracellular cytokine stimulation assays:
  NIH VRC Laboratories
  9 West Watkins Mill Road
  Gaithersburg, MD 20878

- Plaque reduction neutralization test (PRNT):
  Vanderbilt University Medical Center
  Medical Center North D6209
  1161 21st Avenue S
  Nashville, TN 37232

- Live-virus focus-reduction neutralization test (FRNT) and FRNT using mNeonGreen (FRNT-mNG):
  Emory University Yerkes Research Center
  954 Gatewood Road, Room 2054
  Atlanta, GA 30329-4208

- Nanoluciferase neutralization assay:
  University of North Carolina
  3109 Michael Hooker Research Center
  135 Dauer Hill Drive
  Chapel Hill, NC 27599

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A safety monitoring committee (SMC), composed of an independent group of at least 2 to 3 members with appropriate expertise to contribute to the interpretation of data from this study, monitored participant safety and advised the DMID. The SMC members were separate and independent of study staff participating in this study and did not have scientific, financial, or other conflicts of interest related to this study. The SMC met at predefined time points during the study, including if halting criteria were met, and assessed safety throughout the study. Additional details regarding the SMC are provided in Section 3.8.3.2.

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

3.4 Ethical Considerations

3.4.1 Independent Ethics Committee or Institutional Review Board

Each institution that engaged in this study held a current Federalwide Assurance issued by the Office of Human Research Protection (OHRP) for federally funded research. The institutional review board (IRB) registered with OHRP as applicable to the study.

The OHRP-registered IRB reviewed and approved the protocol, associated informed consent documents, recruitment materials, and handouts or surveys intended for the participants, prior to the recruitment, screening, and enrollment of participants. The IRB review was completed in accordance with US Code of Federal Regulations (CFR) Title 45 Part 46 and 21 CFR 50, 21 CFR 56 (IRBs), and other federal, state, and local regulations and policies, as applicable.

The IRB approved amendments to the protocol and informed consent document before they were implemented. The IRB review and approval continued at least annually throughout the duration of the study. The investigator was required to notify the IRB of deviations from the protocol and reportable SAEs, as applicable to the IRB policy.

The DMID received documentation verifying IRB approval of the protocol, informed consent documents, and associated documents prior to the recruitment, screening, and enrollment of participants and any IRB approvals for continuing review or amendments as required by the DMID.

A list of IRBs is provided in Appendix 16.1.3.

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3.4.2 Ethical Conduct of the Study

This study was conducted in conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; 18 April 1979) and the federal policy for the Protection of Human Subjects codified in 45 CFR 46, 21 CFR 50 (Protection of Human Subjects), and the International Council for Harmonisation (ICH) E6(R2) guidelines.

3.4.3 Participant Information and Consent

Investigators or designated research staff obtained a participant's informed consent in accordance with the requirements of 45 CFR 46, 21 CFR 50, and 21 CFR 56 for Food and Drug Administration (FDA)-regulated studies, state and local regulations and policy, and ICH E6 Good Clinical Practice (GCP) before any study procedures or data collection were performed. The investigator or other study staff obtained oral or written information for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant if the process was approved by the IRB. At the first study visit, informed consent was obtained and documented before any study procedures were performed.

Participants received a concise and focused presentation of key information about the clinical study, verbally and with a written consent form. Participants signed the informed consent form (ICF) before any study-specific procedures were performed. Once signed, a copy of the ICF was given to participants for their records.

Participants were asked for consent to collect additional blood, the use of residual specimens, and the sharing of genetic information and samples for secondary research (Section 3.7.4.2). If participants chose not to provide permission for extra blood and secondary research use, they were not eligible for enrollment into the study.

Additionally, to support development of diagnostics, therapeutics, and vaccines, a subset of participants were asked to consent for leukapheresis to collect additional samples for secondary research (Section 3.7.4.1); consent for leukapheresis was not required for study participation.

Full details of the consent process, including additional consent procedures, are provided in 20-0003 Clinical Study Protocol Section 10.1.1 (Appendix 16.1.1).

A sample ICF is provided in Appendix 16.1.3.

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3.5 Selection of Study Population

No exemptions were granted on participant inclusion or exclusion criteria in this DMID-sponsored study.

3.5.1 Inclusion Criteria

A participant must have met all of the following criteria to be eligible to participate in this study:

1. Provided written informed consent prior to initiation of any study procedures.
2. Able to understand and agreed to comply with planned study procedures and was available for all study visits.
3. Agreed to the collection of venous blood per protocol.
4. Male or nonpregnant female, ≥ 18 years of age at time of enrollment.
5. Body mass index (BMI) 18.0 to 35.0 kg/m^2, inclusive (< 56 years of age), at Screening; BMI 18.0 to 30.0 kg/m^2, inclusive (≥ 56 years of age), at Screening.
6. Women of childbearing potential[a] agreed to use or practiced true abstinence[b] or used at least 1 acceptable primary form of contraception.[c,d]

   Note: These criteria were applicable to females in heterosexual relationships and of childbearing potential (ie, the criteria applied to participants in a same sex relationship).

   [a]*Not of childbearing potential – postmenopausal females (defined as having a history of amenorrhea for at least 1 year) or a documented status as being surgically sterile (hysterectomy, bilateral oophorectomy, tubal ligation/salpingectomy, or Essure® placement).*

   [b]*True abstinence is 100% of time no sexual intercourse (male's penis enters the female's vagina). (Periodic abstinence [eg, calendar, ovulation, symptothermal, postovulation methods] and withdrawal were not acceptable methods of contraception.)*

   [c]*Acceptable forms of primary contraception included monogamous relationship with a vasectomized partner who had been vasectomized for 180 days or more prior to the participant's first vaccination, intrauterine devices, birth control pills, and injectable/implantable/insertable hormonal birth control products.*

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[d]*Must have used at least 1 acceptable primary form of contraception for at least 30 days prior to the first vaccination and at least 1 acceptable primary form of contraception for 60 days after the last vaccination.*

7. Women of childbearing potential must have had a negative urine or serum pregnancy test within 24 hours prior to each vaccination.
8. Male participants of childbearing potential[e]: use of condoms to ensure effective contraception with a female partner of childbearing potential from first vaccination until 60 days after the last vaccination.

[e]*Biological males who are postpubertal and considered fertile until permanently sterile by bilateral orchiectomy or vasectomy.*

9. Male participants agreed to refrain from sperm donation from the time of first vaccination until 60 days after the last vaccination.
10. In good health.[f]

[f]*As determined by medical history and physical examination to evaluate acute or ongoing chronic medical diagnoses/conditions that were present for at least 90 days, which would have affected the assessment of safety of participants. Chronic medical diagnoses/conditions should have been stable for the last 60 days (no hospitalizations, emergency room, or urgent care for condition or need for supplemental oxygen). This included no change in chronic prescription medication, dose, or frequency as a result of deterioration of the chronic medical diagnosis/condition in the 60 days before enrollment. Any prescription change that was due to change of health care provider, insurance company, etc, or was done for financial reasons, and in the same class of medication, was not be considered a deviation of this inclusion criterion. Any change in prescription medication due to improvement of a disease outcome, as determined by the participating site investigator or appropriate subinvestigator, was not considered a deviation of this inclusion criterion. Participants may have been on chronic or as needed medications if, in the opinion of the participating site investigator or appropriate subinvestigator, they posed no additional risk to participant safety or assessment of reactogenicity and immunogenicity and did not indicate a worsening of medical diagnosis/condition. Similarly, medication changes subsequent to enrollment and study vaccination were acceptable provided the change was not precipitated by deterioration in the chronic medical condition, and there was no anticipated additional risk to the participant or interference with the evaluation of responses to study vaccination.*

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11. Oral temperature was less than 100.0°F (37.8°C).
12. Pulse was no greater than 100 beats per minute.
13. Systolic blood pressure (BP) was 85 to 150 mm Hg, inclusive.
14. Clinical screening laboratory evaluations (white blood cells [WBCs], hemoglobin [Hgb], platelets [PLTs], alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine [Cr], alkaline phosphatase [ALP], total bilirubin [T. Bili], lipase, prothrombin time, partial thromboplastin time) were within acceptable normal reference ranges at the clinical laboratory being used.
15. Agreed to have samples stored for secondary research.
16. Agreed to adhere to Lifestyle Considerations (defined in Section 3.5.3) throughout study duration.
17. Agreed to refrain from donating blood or plasma during the study (outside of this study).

3.5.1.1 Leukapheresis Inclusion Criteria

A participant must have met all of the following criteria to be eligible for leukapheresis:

1. Provided written informed consent for leukapheresis.
2. Weight ≥ 110 pounds.
3. Screening laboratory evaluations were within acceptable ranges at the site where the leukapheresis procedure was performed.
4. Negative urine or serum pregnancy test within 48 hours of the leukapheresis procedure for women of childbearing potential.
5. Adequate bilateral antecubital venous access.
6. No use of blood thinners, aspirin, or nonsteroidal anti-inflammatory drugs at least 5 days before the leukapheresis procedure.
7. Enrolled in Cohorts 2, 3, 5, 10, or 11 and possibly Cohort 6, if enrolled, and completed the 2-dose vaccination series.

3.5.2 Exclusion Criteria

A participant who met any of the following criteria was excluded from participation in this study:

1. Positive pregnancy test either at Screening or just prior to each vaccine administration.
2. Female participant who was breastfeeding or planned to breastfeed from the time of the first vaccination through 60 days after the last vaccination.

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3. Had any medical disease or condition that, in the opinion of the participating site investigator or appropriate subinvestigator, precluded study participation.[g]

   [g]*Including acute, subacute, intermittent, or chronic medical disease or condition that would have placed the participant at an unacceptable risk of injury, render the participant unable to meet the requirements of the protocol, or may have interfered with the evaluation of responses or the participant's successful completion of this trial.*

4. Presence of self-reported or medically documented significant medical or psychiatric condition(s).[h]

   [h]*Significant medical or psychiatric conditions included but are not limited to:*

   Respiratory disease (eg, chronic obstructive pulmonary disease, asthma) requiring daily medications currently or any treatment of respiratory disease exacerbations (eg, asthma exacerbation) in the last 5 years. Asthma medications: inhaled, oral, or intravenous corticosteroids, leukotriene modifiers, long- and short-acting beta agonists, theophylline, ipratropium, biologics.

   Significant cardiovascular disease (eg, congestive heart failure, cardiomyopathy, ischemic heart disease), history of myocarditis or pericarditis as an adult, myocardial infarction within past 6 months, coronary artery bypass surgery or stent placement, or uncontrolled cardiac arrhythmia.

   Neurological or neurodevelopmental conditions (eg, history of migraines in the past 5 years, epilepsy, stroke, seizures in the last 3 years, encephalopathy, focal neurologic deficits, Guillain-Barré syndrome, encephalomyelitis, transverse myelitis, stroke or transient ischemic attack, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, Creutzfeldt-Jakob disease, or Alzheimer's disease).

   Ongoing malignancy or recent diagnosis of malignancy in the last 5 years excluding basal cell and squamous cell carcinoma of the skin, which were allowed.

   An autoimmune disease, including hypothyroidism without a defined nonautoimmune cause, localized or history of psoriasis.

   An immunodeficiency of any cause.

   Chronic kidney disease, estimated glomerular filtration rate < 60 mL/min/1.73 m^2.

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5. Had an acute illness[i], as determined by the participating site investigator or appropriate subinvestigator, with or without fever (oral temperature ≥ 38.0°C [100.4°F]) within 72 hours prior to each vaccination.

   [i]*An acute illness which was nearly resolved with only minor residual symptoms remaining was allowed if, in the opinion of the participating site investigator or appropriate subinvestigator, the residual symptoms did not interfere with the ability to assess safety parameters as required by the protocol.*

6. Had a positive test result for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus (HIV) types 1 or 2 antibodies at Screening.
7. Participated in another investigational study involving any investigational product[j] within 60 days, or 5 half-lives, whichever was longer, before the first vaccine administration.

   [j]*Study drug, biologic, or device.*

8. Currently enrolled in or planned to participate in another clinical trial with an investigational agent[k] that was to be received during the study reporting period.[l]

   [k]*Included licensed or unlicensed vaccine, drug, biologic, device, blood product, or medication.*

   [l]*13 months after the first vaccination.*

9. Previously participated in an investigational study involving LNPs (a component of the investigational vaccine assessed in this trial).
10. Had a history of hypersensitivity or severe allergic reaction (eg, anaphylaxis, generalized urticaria, angioedema, other significant reaction) to any previous licensed or unlicensed vaccines.
11. Chronic use (more than 14 continuous days) of any medications that may have been associated with impaired immune responsiveness.[m]

    [m]*Included, but not limited to, systemic corticosteroids exceeding 10 mg/day of prednisone equivalent, allergy injections, immunoglobulin, interferon, immunomodulators, cytotoxic drugs, or other similar or toxic drugs during the preceding 6-month period prior to vaccine administration (Day 1). The use of low dose topical, ophthalmic, inhaled, and intranasal steroid preparations was permitted.*

12. Anticipated the need for immunosuppressive treatment within the next 6 months.

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13. Received immunoglobulins and/or any blood or blood products within the 4 months before the first vaccine administration or at any time during the study.
14. Had any blood dyscrasias or significant disorder of coagulation.
15. Had any chronic liver disease, including fatty liver.
16. Had a history of alcohol abuse or other recreational drug (excluding *cannabis*) use within 6 months before the first vaccine administration.
17. Had a positive test result for drugs of abuse at screening or before the first vaccine administration. If cannabis was the only detected drug, inclusion was permitted.
18. Had any abnormality or permanent body art (eg, tattoo) that would interfere with the ability to observe local reactions at the injection site (deltoid region).
19. Received or planned to receive a licensed, live vaccine within 4 weeks before or after each vaccination.
20. Received or planned to receive a licensed, inactivated vaccine within 2 weeks before or after each vaccination.
21. Received any other SARS-CoV-2 or other experimental CoV vaccine at any time prior to or during the study.
22. Had close contact of anyone known to have SARS-CoV-2 infection within 30 days prior to vaccine administration.
23. History of COVID-19 diagnosis.
24. On current treatment with investigational agents for prophylaxis of COVID-19.
25. Current use of any prescription or over-the-counter medications within 7 days prior to vaccination, unless approved by the investigator or necessary to manage a chronic condition.
26. Planned to travel outside the United States (continental United States, Hawaii, and Alaska) from enrollment through 28 days after the second vaccination.
27. Resided in a nursing home or other skilled nursing facility or had a requirement for skilled nursing care.
28. Nonambulatory.
29. For participants ≥ 56 years of age, history of chronic smoking within the prior year.
30. For participants ≥ 56 years of age, current smoking or vaping.
31. For participants ≥ 56 years of age, individuals currently working with high risk of exposure to SARS-CoV-2 (eg, active health care workers with direct patient contact, emergency response personnel).

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3.5.3 Lifestyle Considerations

During this study participants were asked to do the following:

- Refrain from consuming food or drink containing poppy seeds within 72 hours of the screening visit as this could have caused a false positive urine drug screen result
- Follow public health guidance on preventing SARS-CoV-2 infection
- Not eat or drink anything hot or cold within 10 minutes prior to taking oral temperature (Section 3.7.2.5)

3.5.4 Withdrawal of Participants From the Study or Study Vaccine Administration

3.5.4.1 Withdrawal of Participants From the Study

Participants were free to withdraw from participation in the study at any time upon request, without any consequence.

A study participant was withdrawn from participation in the study if any of the following reasons occurred prior to initial dosing:

- Participant requested to terminate participation.
- Study vaccine was not administered.

A participant may have been withdrawn from the study for the following reasons after initial dosing; however, whenever possible the participant should have been followed for safety and immunogenicity evaluations per protocol:

- Participant became pregnant before receiving the second dose of vaccine.
- Study noncompliance to protocol requirements that, in the opinion of the investigator or appropriate subinvestigator, posed an increased risk (eg, missing safety laboratory results) or compromised the validity of the data.
- Lost to follow-up.
- Participant met an exclusion criterion for participation in the study (either newly developed or not previously recognized) that precluded further study participation.

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- Requested by primary care provider, the IRB, FDA, or National Institute of Allergy and Infectious Diseases.
- Medical disease or condition, or new clinical finding(s) for which continued participation, in the opinion of the investigator or appropriate subinvestigator, might have compromised the safety of the participant, interfered with the participant's successful completion of this study, or interfered with the evaluation of responses.
- If any AE, clinical laboratory abnormality, or situation occurred such that continued participation in the study was not be in the best interest of the participant.
- The occurrence of an SAE.

If the participant agreed, every attempt was made to follow all AEs through resolution or stabilization.

A participant was considered lost to follow-up if he or she failed to appear for a follow-up assessment. Extensive effort (ie, generally 3 documented contact attempts via telephone calls, e-mail, or other methods were made on separate occasions) was made to locate or recall the participant, or at least to determine the participant's health status. These efforts were documented in the participant's study file.

The reason for participant withdrawal from the study was recorded on the appropriate data collection form (DCF).

3.5.4.2 Discontinuation of Participants From Study Vaccine Administration

Participants who were not administered any study vaccine were withdrawn from the study (Section 3.5.4.1). Participants who received the first dose of study vaccine were reassessed before receiving the second dose of study vaccine. The following events constituted contraindications to any further administration of study vaccine. If any of these events occurred during the study, the participant did not receive the second dose of study vaccine but was encouraged to continue study participation for safety and immunogenicity evaluations through 12 months after the last dose of study vaccine.

- Withdrawal of consent.

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- As deemed necessary by the investigator or appropriate subinvestigator for noncompliance or other reasons. This may have included previously undisclosed or new conditions that met exclusion criteria.
- Any clinically significant medical condition that, in the opinion of the investigator or appropriate subinvestigator, posed an additional risk to the participant if he or she continued to participate in the study.
- Anaphylaxis or unexpected systemic hypersensitivity reaction following the administration of the first dose of study vaccine.
- Any SAE judged to be related to study vaccine.
- Pregnancy.
- Participant was lost to follow-up.
- New information became available that made further participation unsafe.
- Termination of the study.

Discontinuation of study vaccine administration did not require withdrawal from the study, and the remaining study procedures should have been completed as indicated in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1). If a clinically significant finding was identified after enrollment, including but not limited to changes from baseline, the investigator or qualified designee determined whether any change in participant management was needed. Any new clinically relevant finding was reported as an AE.

3.5.4.3 Replacements

Participants who withdrew, were withdrawn from this study, or were lost to follow-up after signing the ICF (Section 3.5.4.1) and after administration of the study vaccine were not replaced. However, participants who withdrew, were withdrawn from this study, or were lost to follow-up after signing the ICF but before administration of the study vaccine may have been replaced.

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3.6 Study Treatment Groups

3.6.1 Investigational Products Administered

Planned study cohorts are provided in Table 2. Study vaccine administration proceeded in a staged fashion for Cohorts 1 through 8, with enrollment of 4 sentinel participants each in Cohorts 1, 2, and 3, as detailed in Section 3.6.3.

Study vaccine was administered as a 0.5 mL IM injection into the deltoid muscle on a 2-dose injection schedule on Day 1 and Day 29, with a 28-day interval between doses. The second dose of study vaccine was administered preferably in the same arm as the first dose.

mRNA-1273 (0.5 mg/mL) was diluted in 0.9% sodium chloride (NaCl) for injection, United States Pharmacopeia (USP), to obtain 25 µg, 50 µg, 100 µg, and 250 µg in 0.5 mL dosages. The pharmacist prepared the single dose (0.5 mL) for each participant based on cohort assignment. The participating site's research pharmacist performed vaccine preparation on the same day of vaccine administration to the participant. Each dose of study vaccine was administered by a member of the clinical research team that was qualified and licensed to administer the study product.

Participants were observed at the study site for at least 60 minutes after each dose of study vaccine. The injection site was examined immediately prior to each study vaccine administration followed by post vaccination reactogenicity assessments. Any AEs/SAEs were recorded on the appropriate DCF prior to discharge from the study site. The injection site was also examined on Days 8 and 36.

The study followed halting criteria based on events for all participants (Section 3.6.1.1) and for sentinel participants (Section 3.6.1.2). Delay in study vaccine administration if a halting criterion was met was determined per the criteria outlined in Section 3.6.1.3.

Delay of any study vaccine administration was determined per the criteria outlined in Section 3.6.1.4.

3.6.1.1 Halting Criteria

If any of the following events occurred, the study was paused:

1. Any participants experienced an SAE after administration of the vaccine that was considered related to vaccine.

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2. Any participant experienced laryngospasm, bronchospasm, or anaphylaxis within 24 hours after administration of vaccine that was considered related to vaccine.
3. Any participant experienced ulceration, abscess, or necrosis at the injection site that was considered related to vaccine administration.
4. Two or more participants experienced an allergic reaction such as generalized urticaria (defined as occurring at 3 or more body parts) within 72 hours after administration of vaccine that was considered related to vaccine.
5. Three or more participants experienced a grade 3 AE (unsolicited and/or clinical laboratory abnormality), in the same preferred terms (PTs) based on the Medical Dictionary for Regulatory Activities (MedDRA) coding, that lasted at least 48 hours after administration of the vaccine and was considered related to the vaccine. Clinical laboratory abnormalities were not subject to the time window.

Resumption of study vaccine administration and enrollment would only have occurred after review of the AEs that caused the pause and a recommendation to permit further study vaccine administration and enrollment.

3.6.1.2 Sentinel Halting Criteria

If any of the following events occurred in the sentinel participants, the study would have been paused:

1. Any participant experienced ulceration, abscess, or necrosis at the injection site.
2. Any participant experienced laryngospasm, bronchospasm, or anaphylaxis within 24 hours after administration of vaccine.
3. Any participant experienced generalized urticaria (defined as occurring at 3 or more body parts) within 72 hours after administration of vaccine.
4. Any participant experienced an SAE (except for accident or trauma) after administration of the vaccine that was considered related to the vaccine.
5. Any 2 participants in the same cohort experienced the same grade 3 solicited local AE or systemic AE (excluding measured grades of erythema and edema/induration alone) that lasted at least 48 hours within 7 days after administration of the vaccine.
6. Any 2 participants experienced the same grade 3 AE (unsolicited and/or clinical laboratory abnormality), in the same PTs based on the MedDRA coding, that lasted at least 48 hours after administration of the vaccine and was considered related to the vaccine. Clinical laboratory abnormalities were not subject to the time window.

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3.6.1.3 Process for Continuation of Dosing and Redosing

In the event a halting criterion was met, the following were to occur:

- An unscheduled safety analysis by the SMC was required for approval of further enrollment.
- Further administration of the study vaccine, including a second dose, was suspended for ALL participants until an assessment by the SMC occurred.

3.6.1.4 Criteria for Delay of Study Vaccine Administration

If any of the following events occurred at the time scheduled for study vaccine administration, the participant may have been administered the study vaccine at a later date, within the window specified in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1), or the participant may have been discontinued from study vaccine administration at the discretion of the investigator or appropriate subinvestigator (Section 3.5.4.2):

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

Participants with a minor illness without fever, as assessed by the investigator or appropriate subinvestigator, could have had study vaccine administered. Participants with an oral temperature of 38.0°C (100.4°F) or higher were recontacted within the window specified in the Schedule of Activities and re-evaluated for eligibility.

3.6.2 Identity of Investigational Product

mRNA-1273 is a novel LNP-encapsulated mRNA-based vaccine against SARS-CoV-2. mRNA-1273 contains a single mRNA that encodes for S-2P. The mRNA-1273 Drug Product consists of the mRNA formulated in a mixture of 4 ionizable, structural, helper, and PEG lipids common to the ModernaTX's mRNA vaccine platform: SM-102; cholesterol; DSPC; and PEG2000-DMG, respectively.

mRNA-1273 injection was provided as a sterile liquid for injection, white to off-white dispersion in appearance, at a concentration of 0.5 mg/mL in 20 mM tris(hydroxymethyl)aminomethane-hydrochloride buffer containing 87 mg/mL sucrose and 10.7 mM sodium acetate at pH 7.5 (batch number 8520100101). mRNA-1273 was supplied to

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the study sites by ModernaTX via DMID Clinical Materials Services contract (Fisher BioServices).

The USP grade 0.9% NaCl for injection was clear in appearance and provided in 10-mL vials. This product was used to dilute the study vaccine to the desired concentration (Section 3.6.1). The NaCl was supplied to the study sites by Fisher BioServices.

mRNA-1273 and 0.9% NaCl were labeled according to manufacturer specifications and included the statement "Caution: New Drug Limited by Federal Law to Investigational Use."

Further description of the mRNA-1273 and instructions for the receipt, storage, preparation, administration, accountability, and destruction were described in 20-0003 Clinical Study Protocol Section 6.2 (Appendix 16.1.1) and protocol-specific manual of procedures (MOP).

3.6.3 Method of Assigning Participants to Treatment Groups

Enrollment proceeded in a staged fashion after participants consented, demographic data were entered, and participant eligibility was confirmed.

Sentinel participant dosing began with 4 participants in Cohort 1 (25 µg; 18 to 55 years of age). The 4 sentinel participants for Cohort 2 (100 µg; 18 to 55 years of age) were enrolled no earlier than 1 day after enrollment of the last of the 4 sentinel participants in Cohort 1. If no sentinel halting criteria (Section 3.6.1.2) were met after the 8 sentinel participants completed Day 5, full enrollment proceeded first with the remaining participants in Cohort 1 followed by remaining participants in Cohort 2, without interruption. If no halting criteria were met after all participants in Cohort 2 completed Day 8, then dosing of 4 sentinel participants began in Cohort 3 (250 µg; 18 to 55 years of age). If no halting criteria were met after the 4 sentinel participants in Cohort 3 completed Day 5, then full enrollment of Cohort 3 proceeded.

If no halting criteria were met after all participants in Cohorts 1 and 2 completed Day 8 (Section 3.6.1.2), dosing began for Cohorts 4 (25 µg; 56 to 70 years of age) and Cohort 5 (100 µg; 56 to 70 years of age). If no halting criteria were met after all participants in Cohorts 4 and 5 completed Day 8, dosing began for Cohort 7 (25 µg; ≥ 71 years of age) and Cohort 8 (100 µg; ≥ 71 years of age).

If no halting criteria were met after all participants in Cohorts 5 and 8 completed Day 8, dosing began for Cohorts 10, 11, and 12 (50 µg; 18 to 55 years of age, 56 to 70 years of age, and ≥ 71 years of age, respectively); participants were enrolled simultaneously with no staging.

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Based on review of interim safety and immunogenicity data, Cohorts 6 and 9 (250 µg; 56 to 70 years of age and ≥ 71 years of age, respectively) and Cohort 13 (10 µg; 18 to 55 years of age) were not enrolled.

3.6.4 Blinding and Unblinding

This was an open-label study with sequential group enrollment, so randomization and blinding were not utilized.

3.6.5 Treatment Compliance

Each dose of study vaccine was administered by a member of the clinical research team that was qualified and licensed to administer the study product. Administration and date, time, and location of injection were recorded on the appropriate DCF.

3.6.6 Prior and Concurrent Medications and Therapies

Information about prior medications, including hormonal contraceptives, taken by the participant in the 30 days prior to screening were recorded on the appropriate DCF.

Concurrent medications include all medications (prescription, over-the-counter, supplements, and vaccines received outside of the study) taken by the participant from the time the informed consent was signed through Day 394. At each study visit following dosing, including telephone calls, participants were queried about new concurrent medications and changes to existing medications.

Medications that might have interfered with the evaluation of the study vaccine should not have been used by the participant during the study reporting period (12 months after the last dose of study vaccine) unless clinically indicated as part of the participant's health care.

In the event medical conditions dictated the use of medications, participants were encouraged to obtain adequate care, comply with the course of therapy as prescribed by their physician, and inform the investigator as soon as was practical. Any drug or vaccine used or received by the participant during the study was recorded on the appropriate DCF.

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3.7 Safety and Immunogenicity Measurements Assessed and Schedule of Activities

3.7.1 Study Assessments and Schedule of Events

The Schedule of Activities for all participants is presented in 20-0003 Clinical Study Protocol Section 1.2, Table 4 (Appendix 16.1.1).

3.7.1.1 Use of Memory Aid

All participants completed a memory aid from the time of each dose of study vaccine through 7 days post each dose (Days 1 through 8 for the first dose and Days 29 through 36 for the second dose). Memory aids were reviewed with the participants for any AEs (solicited local [injection site] and systemic reactions, as well as unsolicited AEs), SAEs, and concurrent medications during telephone calls as indicated on the Schedule of Activities.

3.7.1.2 Safety Telephone Calls

Participants were contacted by telephone to query for safety events. Any AEs that occurred since the previous clinic visit or telephone call were collected. Based on the information collected, participants may have been asked to return to the study site for evaluation.

3.7.2 Safety Assessments

The primary endpoint in this study was evaluation of the safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart (Section 2). The safety assessments included monitoring and recording the frequency and grade of solicited local and systemic AEs (referred to as ARs when summarized in the results) and unsolicited AEs, the frequency of SAEs and AEs of special interest (AESIs; MAAEs and NOCMCs), as well as clinical laboratory evaluations, vital sign measurements, and physical examinations.

Additionally, safety assessments included reporting of possible AEs associated with leukapheresis (Section 3.7.4.1) and unanticipated problems. The criteria for unanticipated problems and reporting requirements are provided in 20-0003 Clinical Study Protocol Section 8.4 (Appendix 16.1.1).

3.7.2.1 Solicited Adverse Events

Solicited AEs (ie, reactogenicity) were anticipated local and systemic AEs. Solicited AEs were collected from Days 1 through 8 (7 days post first dose) and Days 29 through 36 (7 days post

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second dose) using a memory aid (Section 3.7.1.1). Pre-administration reactogenicity assessments were performed immediately prior to each vaccination to establish baseline. Study clinicians followed and collected resolution information for any reactogenicity symptoms that were not resolved within 7 days.

Solicited AEs included local (injection site) reactions as well as systemic reactions. Solicited systemic AEs included fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), arthralgia (captured in the memory aid as joint pain), nausea, feverishness (captured in the memory aid as chills), and fever. Solicited local AEs included pain at injection site, erythema (captured in the memory aid as redness), and induration (captured in the memory aid as swelling/hardness).

All solicited AEs were assessed, recorded, and followed as described for AEs and for SAEs, if applicable (Section 3.7.2.2).

For consistency across the mRNA-1273 program, these solicited AEs were referred to as solicited ARs when summarized in the results.

3.7.2.2 Unsolicited Adverse Events and Serious Adverse Events

The AE and SAE definitions are provided in the 20-0003 Clinical Study Protocol Section 8.3.1 and Section 8.3.2 (Appendix 16.1.1). Adverse events were further divided into solicited AEs and unsolicited AEs. Solicited AEs were those the study team specifically queried the participant about (Section 3.7.2.1). Unsolicited AEs were those events that the participant reported without being queried about the specific event. All unsolicited AEs were reported spontaneously by the participant and/or in response to open questions from study staff or revealed by observation, physical examination, or other diagnostic procedures.

This study also included the following AESIs: MAAEs and NOCMCs (Section 3.7.2.2.1). The possible AEs associated with the leukapheresis procedure were reported for those participants who consented for leukapheresis (Section 3.7.4.1). Details regarding these AEs are provided in 20-0003 Clinical Study Protocol Section 8.3.1.3 (Appendix 16.1.1).

All AEs (unsolicited AEs, SAEs, and AESIs [MAAEs and NOCMCs]), were captured on the appropriate DCF. All AEs were described in terms of duration (start and stop date), severity, association with the study vaccine, action(s) taken, and outcome. All AEs were followed to resolution or stabilization.

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All clearly related signs, symptoms, and results of diagnostic procedures performed because of an AE were grouped together and recorded as a single diagnosis. If the AE was a clinical laboratory abnormality that was part of a clinical condition or syndrome, it was recorded as the syndrome or diagnosis rather than the individual clinical laboratory abnormality. Any AEs characterized as intermittent required documentation of onset and duration of each episode. Changes in the severity of an AE were documented to allow an assessment of the duration of the event at each level of intensity.

All AEs that occurred during the study collection and reporting period were documented appropriately regardless of relationship and were followed to resolution or stabilization.

Unsolicited AEs (including SAEs and AESIs) were collected from the time of study vaccine administration on Day 1 through Day 57. After Day 57 and through the end of the study (Day 394), only SAEs and AESIs were collected and reported. All SAEs were reviewed and evaluated by the DMID and were sent to the SMC (for periodic review unless related) and IRB.

Additional information on documenting and reporting AEs, SAEs, and AESIs as well as assessment of severity and relationship to study vaccine are provided in the 20-0003 Clinical Study Protocol Section 8.3 (Appendix 16.1.1).

3.7.2.2.1 Adverse Events of Special Interest

Nonstructured data similar to SAEs were collected for AESIs. The following were identified as AESIs for this study:

- NOCMC: Defined as any new International Statistical Classification of Diseases diagnosis (per current International Statistical Classification of Diseases and Related Health Problems) that was applied to the participant during the course of the study, after receipt of the study agent, that was expected to continue for at least 3 months and that required continued health care intervention

- MAAE: Defined as hospitalization, an emergency room visit, or an otherwise unscheduled visit to or from medical personnel for any reason

The MAAEs and NOCMCs were collected from Day 1 through the end of the study (Day 394).

An assessment for new medical conditions and symptoms suggestive of MAAEs and NOCMCs could have been obtained as part of the collection of participant interim medical

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history, which was obtained by interviewing the participants and asking about any changes since the previous clinic visit or telephone contact.

All AESIs were assessed, recorded, and followed as described for AEs and for SAEs, if applicable (Section 3.7.2.2).

3.7.2.3 Pregnancy

Pregnancy was not considered an AE. However, any pregnancy that occurred during study participation (through Day 394) was reported to the sponsor on the appropriate DCF. Pregnancy should have been followed to outcome.

3.7.2.4 Clinical Laboratory Evaluations

Clinical laboratory evaluations, including screening evaluations and pregnancy testing, were performed locally by the study site laboratory.

The following clinical safety laboratory evaluations were performed at screening and at the time points indicated in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1). Laboratory samples collected immediately before the first dose of study vaccine served as baseline (Day 1).

Hematology and chemistry: WBC count, Hgb, PLTs, ALT, AST, ALP, T. Bili, Cr, lipase, prothrombin time (Screening only), and partial thromboplastin time (Screening only)

Pregnancy test: Serum pregnancy testing was performed at the screening visit, and urine or serum pregnancy testing was performed within 24 hours before each dose of study vaccine on Days 1 and 29, and as needed at interim or unscheduled visits for all women of childbearing potential. Negative results must have been confirmed before enrollment on Day 1 and before administration of each dose of study vaccine.

Additionally, the following laboratory evaluations were performed at screening only:

Serology: hepatitis B surface antigen, hepatitis C virus antibody, and HIV types 1 and 2 antigen/antibody

Urine drug screen: testing for drugs of abuse (components per the standard panel at the study site laboratory)

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3.7.2.5 Vital Sign Measurements

Vital sign measurements included systolic and diastolic BP, heart rate, and oral temperature and were measured at time points specified in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1). On Days 1 and 29, vital sign measurements were collected before vaccine administration. Vital signs assessed before the first dose of study vaccine on Day 1 were considered as baseline.

3.7.2.6 Physical Examinations

A full physical examination was performed at the screening visit, and a symptom-directed (targeted) physical examination was performed at all other time points, as specified in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1).

A full physical examination included assessments of the following organs and organ systems: skin; head, eyes, ears, nose, and throat; neck; lungs; heart; liver; spleen; abdomen; extremities; lymph nodes (axillary and cervical); and nervous system. Height and weight were measured and BMI was calculated at the screening visit only.

A symptom-directed (targeted) physical examination should have included an assessment for signs suggestive of MAAEs and NOCMCs. Interim or unscheduled physical examinations were performed at the discretion of the investigator or appropriate subinvestigator, if necessary, to evaluate AEs or abnormal clinical laboratory test results.

3.7.3 Immunogenicity Assessments

The secondary and exploratory immunogenicity endpoints are provided in Section 2. Blood samples for immunogenicity assessments were collected at the time points indicated in the Schedule of Activities (20-0003 Clinical Study Protocol Section 1.2, Table 4; Appendix 16.1.1).

The following serological immunogenicity assays were performed:

- IgG ELISA to the SARS-CoV-2 S protein
- Immunoglobulin M (IgM) and immunoglobulin A (IgA) ELISA to the SARS-CoV-2 S protein (planned)
- Neutralization assay using a SARS-CoV-2 pseudovirus

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- Neutralization assay using a live wild-type SARS-CoV-2

The assessment of IgM and IgA ELISA to the SARS-CoV-2 S protein have not yet been performed and are not reported in this Day 119 interim CSR. If conducted, these results will be reported in the final CSR.

This study also investigated T-cell immune responses using multiparametric flow cytometry.

Preparation of blood samples and shipping instructions for serological immunogenicity assays and cellular immunology assays were outlined in the protocol-specific MOP.

3.7.4 Other Assessments: Future Testing

3.7.4.1 Leukapheresis

To support development of diagnostics, therapeutics, and vaccines, a subset of enrolled participants who provided separate consent underwent leukapheresis to collect additional samples for secondary research. This was an outpatient procedure during which leukocytes were selectively harvested; red cells and other blood components were returned to the participant.

For participants who consented for leukapheresis, screening procedures, including screening laboratory evaluations, were performed locally before the leukapheresis procedure. Details on the leukapheresis procedure are provided in 20-0003 Clinical Study Protocol Section 8.2, (Appendix 16.1.1) and in the protocol-specific MOP.

Safety monitoring included possible AEs related to leukapheresis (Section 3.7.2.2).

Results of leukapheresis evaluation are not reported in this Day 119 CSR.

3.7.4.2 Genetic/Genomic Analysis

Stored PBMCs, including leukocyte samples obtained by leukapheresis, may be used in secondary research for sequencing of DNA from B cells to characterize B cell receptors and monoclonal antibodies. The DNA data may be used to synthesize antigen-specific antibodies to characterize antibody binding. Secondary research samples may also be used for other genomic analysis, including but not limited to, single nucleotide polymorphisms arrays, human leukocyte antigen typing, transcriptomic analysis, evaluation of the immune response to the vaccine, and/or evaluation of any AE from the vaccine.

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Results of genetic/genomic evaluation are not reported in this Day 119 CSR.

3.7.5 Appropriateness of Measurements

The measures of safety used in this study were routine clinical procedures and laboratory assessments. They included a close vigilance for, and stringent reporting of, selected local and systemic reactions routinely monitored in clinical studies of IM vaccines as indicators of reactogenicity.

The measures of immunogenicity used in this study were standard, ie, widely used and generally recognized as reliable, accurate, and relevant (able to describe the quality and extent of the immune response) for an investigational vaccine clinical study.

3.8 Data Quality Assurance

To ensure the reliability of study data, each participating study site developed a Clinical Quality Management Plan (CQMP). The CQMP described the following:

- Routine internal quality control and quality assurance activities
    - For the purposes of measuring, documenting, and reporting study conduct, protocol adherence, human subjects' protections, and reliability of the protocol-driven data collected
    - Independent of sponsor's study site monitoring
- A process for addressing data quality issues (ie, collecting, recording, and reporting findings in a timely manner), systemic issues (ie, protocol conduct, noncompliance, human subject protections), and implementation and evaluation of corrective and preventative action plan procedures

3.8.1 Data Collection and Management

Data collection was the responsibility of the study staff at the participating study site under the supervision of the investigator. The investigator was required to maintain complete and accurate source documentation.

Clinical research data from source documentation, including, but not limited to, AEs/SAEs, concurrent medications, medical history, physical assessments, and clinical laboratory data, was entered by the participating study site into electronic case report forms via a

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21 CFR Part 11-compliant internet data entry system provided by the SDCC. The data system included password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

3.8.2 Study Monitoring

Clinical site monitoring was conducted to ensure that the rights and well-being of study participants were protected and that the reported study data were accurate, complete, and verifiable. Clinical site monitoring also ensured that the conduct of the study was in compliance with the currently approved protocol and amendment(s), ICH, GCP, and with applicable regulatory and sponsor requirements. Clinical site monitoring also verified that any critical study procedures were completed following specific instructions in the protocol-specific MOP.

Monitoring for this study was performed by the DMID. Details of clinical site monitoring are documented in a clinical monitoring plan (CMP).

3.8.3 Safety Oversight

3.8.3.1 Protocol Team

The protocol team, which included representatives from the participating study site (investigator), the DMID (sponsor), VRC, and ModernaTX, met at predefined time points to review AE data and to ensure no halting criteria had been met.

3.8.3.2 Safety Monitoring Committee

Safety oversight included an SMC, composed of an independent group of at least 2 to 3 experts that monitored participant safety and advised the DMID. The SMC members were separate and independent of study staff participating in this study and did not have scientific, financial, or other conflicts of interest related to this study. The SMC consisted of members with appropriate expertise to contribute to the interpretation of data from this study.

The SMC met before enrollment and if the halting criteria were met. Materials were provided electronically. The SMC could also have met if requested by the sponsor or investigator.

Procedures for SMC reviews/meetings were defined in the SMC charter. The SMC reviewed applicable data, including, but not limited to, enrollment, demographics, dosing data, clinical laboratory data, and safety data, at scheduled time points during this study as defined in the SMC charter.

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Additional data and interim statistical reports as deemed necessary and appropriate by the DMID could have been requested by the SMC. As an outcome of each review/meeting, the SMC made recommendations regarding proceeding with study vaccine administration and continuing, modifying, or terminating the study.

3.8.4 Risk Management

This study was conducted according to ICH E6(R2) risk and quality processes. Throughout the project lifecycle, risks to study implementation and execution due to the pandemic were reviewed and mitigation plans were developed. Risk-based monitoring was implemented as documented in the DMID monitoring manual.

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

4.1 Statistical Methods

4.1.1 General Considerations

All continuous variables were summarized using the following descriptive statistics: n (nonmissing sample size), mean, SD, median, maximum, and minimum. The frequency and percentages (based on the nonmissing sample size) of observed levels were reported for all categorical measures. In general, all data were listed; sorted by study site, treatment, and participant; and, when appropriate, by visit number with participant. Summary tables were structured with a column for each treatment and were annotated with the total population size relevant to that table/cohort, including any missing observations.

4.1.2 Determination of Sample Size

Rare AEs are not demonstrable in a clinical study of this size. The probabilities of observing 1 or more AEs given various true event rates are presented in 20-0003 Statistical Analysis Plan Section 5 (Appendix 16.1.9). With the assumption that all enrolled participants were likely to complete immunizations and safety visits in this relatively short duration study, the following statistical considerations applied. With 15 participants in each dose group (Cohorts 1 to 3, 10, and 13), the chance of observing at least 1 AE of probability 20% or more was approximately 97%. Therefore, if no AEs of a given type occurred in a dose group (Cohorts 1 to 3, 10, and 13), one can be relatively confident that they will occur in fewer than 20% of people once the vaccine is implemented. With 60 participants across these 4 dosing cohorts (1 to 3, and 10), the chance of observing at least 1 AE of probability 5% or more was at least 95%. Therefore, if no AEs of a given type occurred across the combined doses, one can be very confident that any dosage-independent event will occur in fewer than 5% of people once the vaccine is implemented. With 10 participants in each dose group (Cohorts 4 through 9, 11, and 12), the chance of observing at least 1 AE of probability 20% or more was approximately 89.3%. Therefore, if no AEs of a given type occurred in a dose group (Cohorts 4 through 9, 11, and 12), one can be relatively confident that they will occur in fewer than 20% of people once the vaccine is implemented in the older population. With 30 participants across each of the 2 older participant dosing cohorts (ie, Cohorts 4, 5, and 11 and Cohorts 7, 8, and 12), the chance of observing at least 1 AE of probability 5% or more was at least 78.5%. Therefore, if no AEs of a given type occurred across the combined doses, one can be very confident that any

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dosage-independent event will occur in fewer than 5% of older people once the vaccine is implemented.

4.1.3 Analysis Sets

4.1.3.1 Modified Intention-to-Treat (mITT) Population

The modified intent-to-treat (mITT) population included all participants who received 1 dose of vaccine and contributed both pre- and at least 1 post-dose venous blood samples for immunogenicity testing for which valid results were reported.

4.1.3.2 Per-Protocol Population

Protocol deviations were reviewed to determine which protocol deviations may have affected the analysis. The per-protocol (PP) population was then defined, and this included all participants in the mITT subset with the following exclusions:

- Data from all available visits for participants found to be ineligible at baseline
- Data from all visits subsequent for the protocol deviations that were considered to affect the science
- Data from any visit that occurred substantially out of window

4.1.3.3 Safety Population

The safety analysis population included all participants who received 1 dose of vaccine.

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

Missing data were not imputed.

For neutralization assays, any percent neutralization below zero was imputed as zero for modeling purposes.

4.1.5 Interim Analyses and Data Monitoring

Cumulative safety information, study status, and primary endpoint results may have been published, presented at a public forum, or presented as summaries aggregated by study arm at the discretion of the sponsor while the primary study was ongoing. Any ad hoc analyses, jointly developed by the SDCC and/or the VRC and ModernaTX, were executed by the SDCC, as

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needed. None of the interim analyses included any formal statistical hypothesis testing; therefore, *p* value adjustment was not made to any analyses.

The SMC reviewed cumulative AE data after all participants in Cohorts 1 and 2 completed Day 8. In addition, cumulative AE data were provided to the SMC after all participants in Cohorts 3, 4, 5, 7, and 8 completed Day 8. Cumulative AE data were also provided to the SMC after all participants in all cohorts completed Day 57. Documentation of review and any concerns noted were solicited electronically.

For public health reasons, several immunogenicity reviews were performed. The following reviews occurred once data were available:

- For sentinel participants in Cohorts 1 and 2, the ELISA IgG data through Day 29
- For all participants in Cohorts 1 and 2, the ELISA IgG data through Day 29
- For sentinel participants in Cohort 3, the ELISA IgG data through Day 29
- For all participants in Cohort 3, the ELISA IgG data through Day 29
- For all participants in Cohorts 4, 5, 7, and 8, the ELISA IgG data through Day 29
- For all participants in Cohorts 10, 11, and 12, ELISA IgG data through Day 29
- For sentinel participants in Cohorts 1 and 2, the ELISA IgG data through Day 57
- For all participants in Cohorts 1 and 2, the ELISA IgG data through Day 57
- For sentinel participants in Cohort 3, the ELISA IgG data through Day 57
- For all participants in Cohort 3, the ELISA IgG data through Day 57
- For all participants in Cohorts 4, 5, 7, and 8, the ELISA IgG data through Day 57
- For all participants in Cohorts 10, 11, and 12, ELISA IgG data through Day 57

Additional data review of immunogenicity may have been performed to inform public health decisions.

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Data were disseminated to public health officials and partners as needed and included in scientific publications and presentations to inform the global scientific community.

An interim analysis of safety, reactogenicity, and immunogenicity data was planned once all participants in Cohorts 1 through 5, 7, and 8 completed Day 119 and Cohorts 10 through 12 completed Day 57, and the data were entered in the study database, validated, and monitored according to the CMP.

4.1.6 Multiplicity Adjustments

There were no adjustments planned for multiple comparisons.

4.1.7 Multicenter Studies

Data were pooled across all clinical sites. Center effects were not anticipated because the sites used standardized procedures for administration of the study vaccine and assessment of solicited and unsolicited AEs, and the study relied on central laboratories for the assessment of immunogenicity.

4.1.8 Adjustment for Covariates

Not applicable.

4.1.9 Examination of Subgroups

The protocol did not define any formal subgroup analyses, and the study was not adequately powered to perform subgroup analyses.

4.1.10 Active-Control Studies Intended to Show Equivalence

No active comparator groups were used in this study.

4.2 Population, Efficacy, and Safety Statistical Analyses

4.2.1 Study Population

4.2.1.1 Disposition

The disposition of participants in the study was tabulated by vaccination group. A flowchart showing the disposition of study participants, adapted from the Consort Statement was included. This figure presented the number of participants screened, enrolled, lost to follow-up, and analyzed by vaccination group.

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4.2.1.2 Protocol Deviations

A summary of participant-specific protocol deviations including major deviations were presented by the reason for the deviation, the deviation category, and vaccination group for all participants.

4.2.1.3 Demographics and Baseline Characteristics

Summaries of age, sex, ethnicity, and race were presented by vaccination group.

4.2.1.4 Prior and Concurrent Medical Conditions

All current illnesses and past pre-existing medical conditions were coded using MedDRA, (version 23.0 or higher). All prior and concurrent medical conditions were presented by participant in a listing.

4.2.1.5 Prior and Concurrent Medications

Summaries of medications that were started before dosing and continuing at the time of dosing were presented by WHO drug code Levels 2 and 3 and vaccination group. The use of concurrent medications during the study were summarized by Anatomical Therapeutic Chemical code level 1, Anatomical Therapeutic Chemical code level 2, and vaccination group for the safety population.

Individual participant listings were presented for all prior and concurrent medications.

4.2.1.6 Exposure and Treatment Compliance

The number of doses of study vaccine administered to participants was presented by vaccination group as part of the participant disposition table.

4.2.2 Safety Analyses

4.2.2.1 Adverse Events

When calculating the incidence of AEs (ie, on a per participant basis), each participant was only counted once, and any repetitions of AEs within a participant were ignored; the denominator was the total population size. All AEs were included in the summaries and analyses.

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4.2.2.1.1 Solicited Events and Symptoms

Solicited AEs (ie, reactogenicity) were anticipated local and systemic AEs. Systemic solicited AEs were collected before vaccine administration, and systemic and local solicited AEs were collected 30 minutes after vaccine administration and then daily for 7 days after each injection and graded on a scale of 0 (absent), 1 (mild), 2 (moderate) and 3 (severe) using a memory aid.

Systemic AEs included fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), arthralgia (captured in the memory aid as joint pain), nausea, feverishness (captured in the memory aid as chills), and fever.

Local AEs included pain at injection site, erythema (captured in the memory aid as redness), and induration (captured in the memory aid as swelling/hardness).

For consistency across the mRNA-1273 program, these solicited AEs were referred to as solicited ARs when summarized in the results.

The proportion of participants reporting at least 1 solicited AR was summarized for each solicited AR, any systemic symptom, any local symptom, and any symptoms. The 95% confidence interval (CI) was calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option).

For each systemic and local event, any systemic event, any local event, and any solicited event, the maximum severity over 7 days after each dose of study vaccine was summarized for the safety population. The number and percentage of participants reporting each event were summarized by the maximum severity and vaccination group, separately for each dose and over all doses. For each event the denominator was the number of participants with nonmissing data for the specific event.

The number of participants reporting a solicited AR were summarized for each day post dose for each dose of study vaccine and for all doses of study vaccine combined both in a summary table and graphically in a bar chart.

The mean, SD, median, minimum, and maximum duration of solicited ARs were summarized. Day of solicited symptom onset and maximum severity on the day of onset were summarized graphically.

Solicited ARs by participant were presented in a listing.

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4.2.2.1.2 Unsolicited Adverse Events

The proportion of participants reporting at least 1 unsolicited AE was summarized by MedDRA system organ class (SOC) and PT for each dose of study vaccine and over all doses. Denominators for percentages were the number of participants who received the dose of study vaccine being summarized.

Unsolicited AEs by participant were presented in a listing.

The following summaries for unsolicited AEs were presented by MedDRA SOC, PT, dose, and vaccination group:

- Participant incidence and total frequency of unsolicited AEs
- Summary of severity and relationship to study vaccine
- Participant incidence and total frequency of related unsolicited AEs over time
- Participant listing of nonserious AEs of moderate or greater severity
- Listing of other MAAE and NOCMC
- Bar chart of nonserious related AEs by severity and MedDRA SOC
- Bar chart of nonserious related AEs by severity

4.2.2.1.3 Deaths, Serious Adverse Events, and Other Significant Adverse Events

Deaths, SAEs, NOCMCs, and MAAEs were presented in listings.

4.2.2.2 Clinical Laboratory Evaluations

The distribution of clinical laboratory results by severity, time point, and vaccination group was presented. Descriptive statistics (mean, SD, median, minimum, and maximum) were summarized by time point for each laboratory parameter. Participant visits with abnormal laboratory results, grade 1 severity or higher, were presented. A complete listing of individual clinical laboratory results with applicable reference ranges was presented.

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4.2.2.3 Vital Signs and Physical Examinations

Vital signs were tabulated by visit and vaccination group.

The change in physical examination data from Day 1 was summarized for each visit by vaccination group.

4.2.2.4 Pregnancies

The total number of pregnancies; number of live births; and number of spontaneous abortions, elective abortions, or still births were summarized by vaccination group. Pregnancies and outcomes were presented in a listing.

4.2.3 Immunogenicity Analyses

4.2.3.1 Primary Immunogenicity Analysis

Refer to Section 4.2.2 for safety analyses which are the primary endpoints of this study.

4.2.3.2 Secondary Immunogenicity Analysis

Summaries and analysis of secondary immunogenicity data were presented for the PP population.

Seroconversion was defined as a 4-fold increase in antibody titer over baseline.

Seroconversion rates, geometric mean fold rise (GMFR), geometric mean titer (GMT), and Williams mean of the area under the curve (AUC) for SARS-CoV-2 (S-2P and receptor binding domain [RBD]) as measured by IgG ELISA were calculated on Days 1 (GMT only) and 57 by cohort and were summarized graphically. Seroconversion rates, GMFR, GMT, and Williams mean of the AUC were presented with their corresponding 95% CI estimates (using Student's t-distribution) at each time point. The AUC was calculated using the trapezoidal method applied to a serial dilution curve. For samples with an AUC of zero at baseline, fold rise was calculated by dividing post-dose result by the lowest reported value. Only endpoint titer values are reported in this Day 119 CSR.

4.2.3.3 Exploratory Immunogenicity Analyses

Summaries and analysis of exploratory immunogenicity data were presented for the PP population.

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4.2.3.3.1 SARS-CoV-2–Specific bAb

Seroconversion rates, GMFR, GMT, and Williams mean of AUC for SARS-CoV-2 (S-2P and RBD) as measured by IgG ELISA were calculated for specified time points by cohort and analyzed and presented according to the same methods as the secondary endpoint (Section 4.2.3.2).

4.2.3.3.2 SARS-CoV-2–Specific nAb

The SARS-CoV-2 PsVNA and a wild-type SARS-CoV-2 PRNT were performed using serial dilutions of sera. The serum dilution required to achieve 50% and 80% neutralization (ID_{50} and ID_{80}, respectively) were calculated for PsVNA data using a 5-parameter logistic regression model and were summarized by group using the geometric mean (GM) and 95% CI (using Student's t-distribution). Similarly, for PRNT data, 80% PRNT ($PRNT_{80}$) was calculated using a 5-parameter logistic model and was summarized using a GM and 95% CI. The minimum, median, and maximum were also reported. Neutralization endpoints were also displayed graphically on a $\log_2$ scale or a $\log_{10}$ scale.

Similar methods were used to summarize all additional neutralization assays performed (eg, a live-virus FRNT and FRNT-mNG). Spearman correlation between various neutralization assays were assessed.

4.2.3.3.3 Cell-Mediated Immune Response

The magnitude, phenotype, and percentage of cytokine-producing S protein-specific T cells were summarized at each time point by vaccination group.

4.3 Changes to the Planned Analyses

The Day 119 CSR was not originally planned as an interim analysis; however, due to public health needs (submission to the FDA) the interim analysis was added. The protocol and statistical analysis plan were both updated to outline which planned analysis would be included in this Day 119 CSR.

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5 Study Populations

The results reported in this CSR include interim analysis of safety and immunogenicity data through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10, 11, and 12 (Table 2). Results in this CSR are presented and discussed primarily by age groups (18 to 55 years, 56 to 70 years, and ≥ 71 years). All tables are summarized by dose levels and overall and are presented by age groups.

5.1 Disposition of Participants

A total of 256 potential participants were screened across all age groups, and 120 participants were enrolled. All participants received the first injection, and 116 participants received the second injection; 4 participants discontinued the vaccine after the first injection and these participants were excluded from the PP population (Listing 5). No participant discontinued from the study at the time of data cutoff. All participants in Cohorts 10, 11, and 12 completed the planned follow-up visits through Day 57, and all participants in Cohorts 1 through 5, 7, and 8 completed the planned follow-up through Day 119.

Age Group: 18 to 55 Years

A total of 60 participants were enrolled into the 18 to 55 years of age group (15 participants each in the 25 µg, 50 µg, 100 µg, and 250 µg vaccination groups). All 60 (100%) participants received the first injection, and 57 (95%) participants received the second injection (Table 4). Three participants discontinued the treatment after the first injection: 1 participant in the 25 µg vaccination group met exclusion criterion 22 (potential COVID-19 exposure), and 2 participants (1 each in the 25 µg and 250 µg vaccination groups) discontinued due to AEs (Section 7.3.3.1). A flowchart of participant disposition for participants enrolled into the 18 to 55 years of age groups is presented in Figure 1.

Age Group: 56 to 70 Years

A total of 30 participants were enrolled into the 56 to 70 years of age group (10 participants each in the 25 µg, 50 µg, and 100 µg vaccination groups). All 30 (100%) participants received the first injection, and 29 (97%) participants received the second injection (Table 5). One participant in the 100 µg vaccination group discontinued the treatment after the first vaccination due to an AE (Section 7.3.3.1). A flowchart of participant disposition for participants enrolled into the 56 to 70 years of age groups is presented in Figure 2.

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Age Group: ≥ 71 Years

A total of 30 participants were enrolled into the ≥ 71 years of age group (10 participants each in the 25 µg, 50 µg, and 100 µg vaccination groups); all 30 (100%) participants received 2 injections of vaccine (Table 6). A flowchart of participant disposition for participants enrolled into the ≥ 71 years of age groups is presented in Figure 3.

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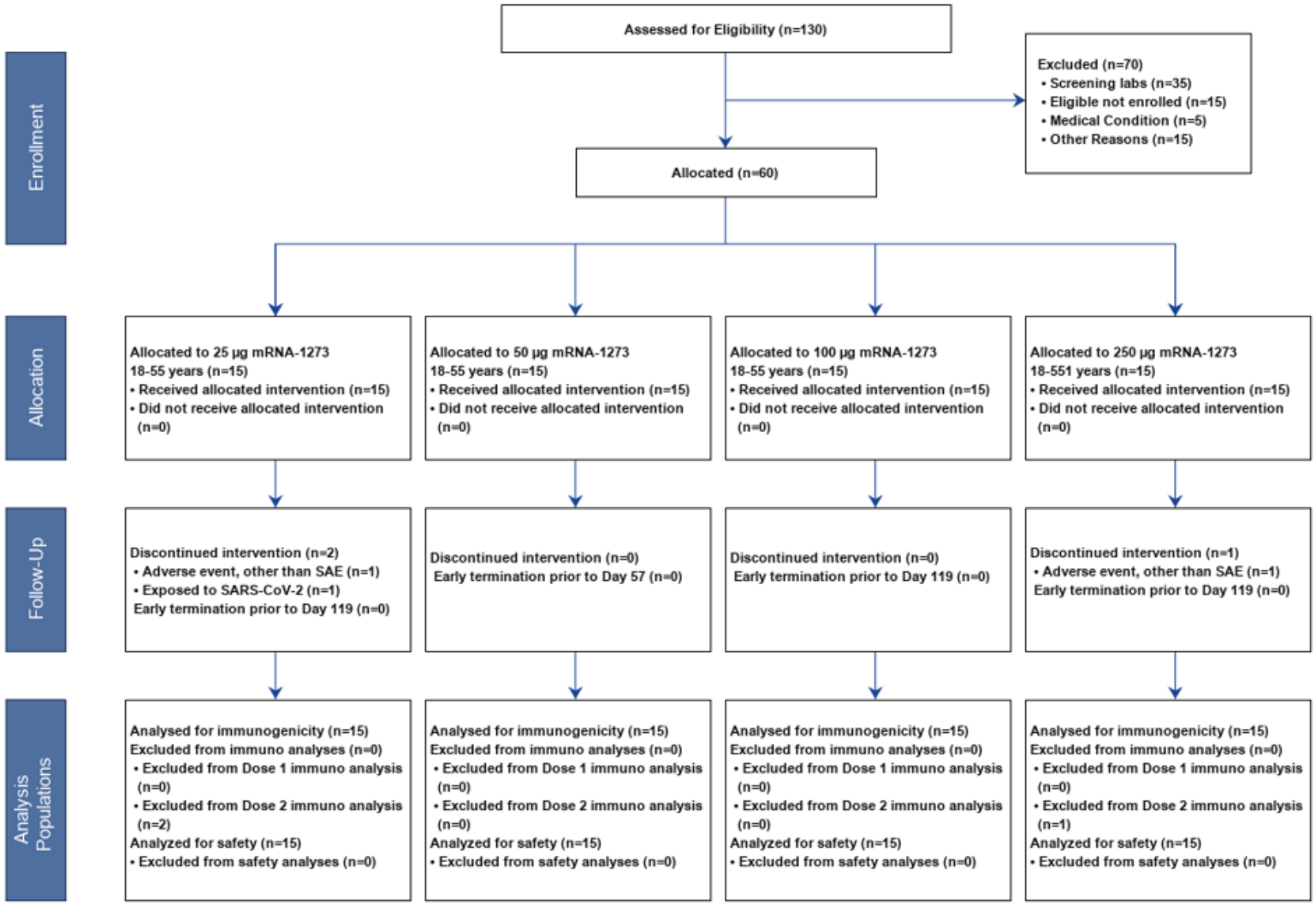
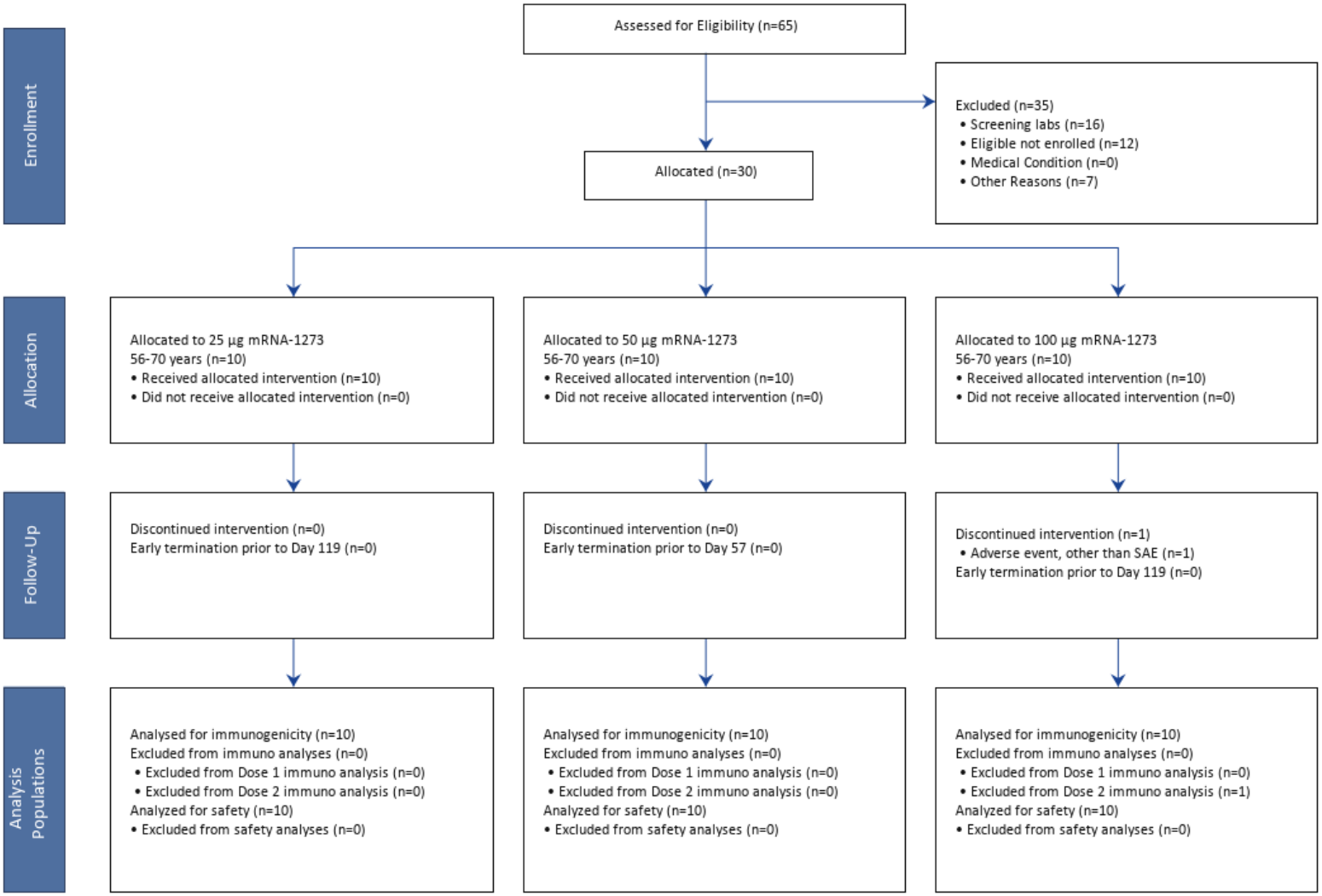
Figure 1: Consort Flow Diagram (All Participants 18 to 55 Years of Age)



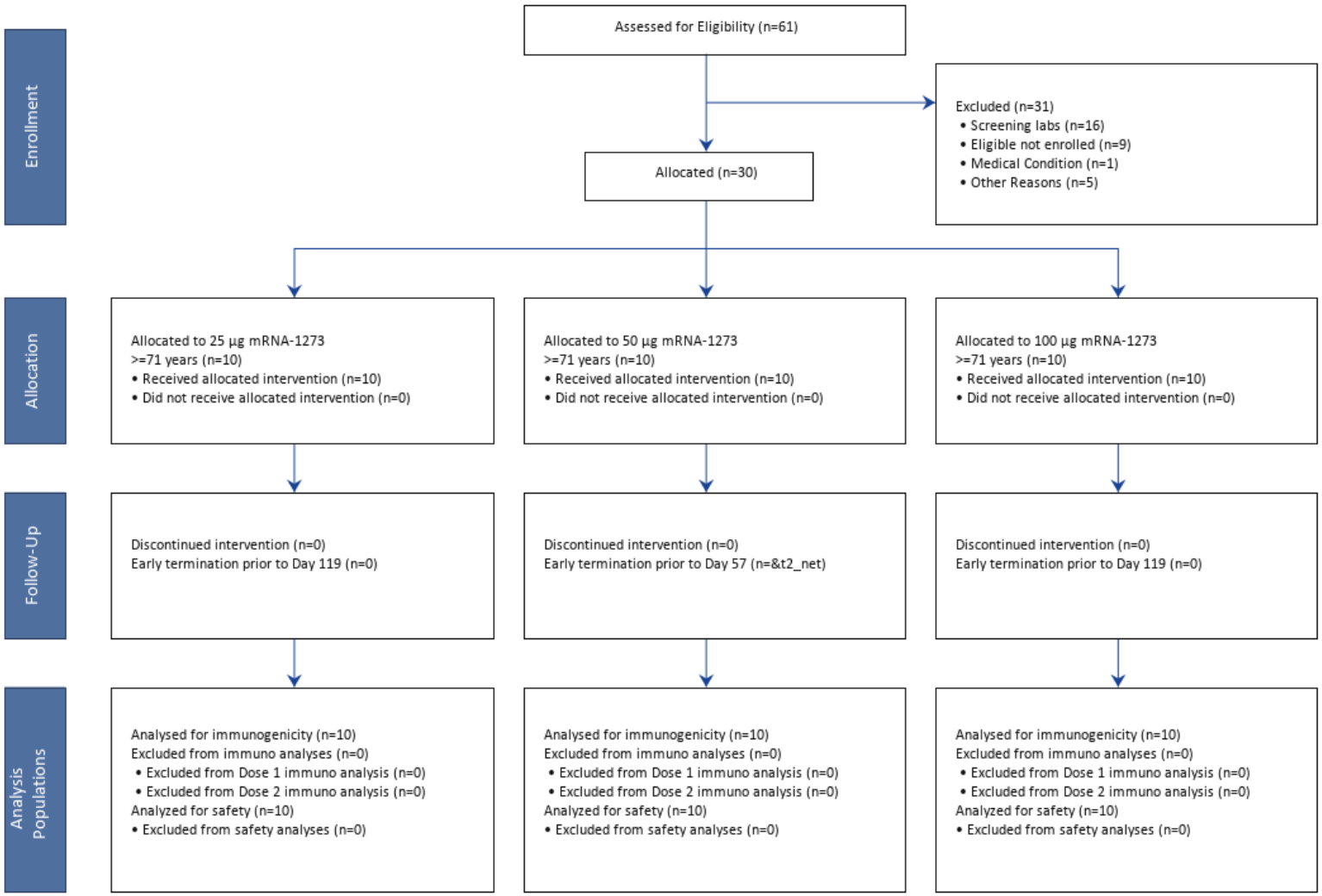
Abbreviations: immuno = immunogenicity; SAE = serious adverse event; SARS-CoV-2 = 2019 novel coronavirus
Source: Posttext Figure 1.

Figure 2: Consort Flow Diagram (All Participants 56 to 70 Years of Age)



Abbreviations: immuno = immunogenicity; SAE = serious adverse event
Source: Posttext Figure 2.

Figure 3: Consort Flow Diagram (All Participants ≥ 71 Years of Age)



Abbreviation: immuno = immunogenicity
Source: Posttext Figure 3.

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Table 4: Summary of Participant Disposition (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Levels				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Screened	–	–	–	–	–
Enrolled, n (%)	15 (100)	15 (100)	15 (100)	15 (100)	60 (100)
Received the first vaccination, n (%)	15 (100)	15 (100)	15 (100)	15 (100)	60 (100)
Discontinued treatment	2 (13)	–	–	1 (7)	3 (5)
Received the second vaccination, n (%)	13 (87)	15 (100)	15 (100)	14 (93)	57 (95)
Discontinued treatment	2 (13)	–	–	1 (7)	3 (5)
Study ongoing, n (%)	15 (100)	15 (100)	15 (100)	15 (100)	60 (100)
Early termination, n (%)	–	–	–	–	–
Completed study	–	–	–	–	–

Source: Posttext Table 1.

Table 5: Summary of Participant Disposition (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			All Participants (N=30)
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	
Screened	–	–	–	–
Enrolled, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Received the first vaccination, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Discontinued treatment	–	–	1 (10)	1 (3)
Received the second vaccination, n (%)	10 (100)	10 (100)	9 (90)	29 (97)
Discontinued treatment	–	–	1 (10)	1 (3)
Study ongoing, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Early termination, n (%)	–	–	–	–
Completed study	–	–	–	–

Source: Posttext Table 2.

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Table 6: Summary of Participant Disposition (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Screened	–	–	–	–
Enrolled, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Received the first vaccination, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Discontinued treatment	–	–	–	–
Received the second vaccination, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Discontinued treatment	–	–	–	–
Study ongoing, n (%)	10 (100)	10 (100)	10 (100)	30 (100)
Early termination, n (%)	–	–	–	–
Completed study	–	–	–	–

Source: Posttext Table 3.

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5.2 Protocol Deviations

None of the protocol deviations reported were considered to have significantly affected the conduct of the study.

A protocol deviation for breach of confidentiality in the 18 to 55 years of age group was considered a major protocol deviation. The protocol deviation was noted on Study Day -4. The deviation did not affect the participation in the study and the participant was not excluded from any analyses on the basis of this protocol deviation (Listing 3). All other deviations reported in each age group were not considered major deviations. (Posttext Table 12, Posttext Table 13, and Posttext Table 14).

Additionally, there was one nonparticipant-specific major protocol deviation reported. The deviation included inadvertent disclosure of study participation by one participant to other study participants via e-mail (Listing 4).

5.3 Demographics and Other Baseline Characteristics

Demographic data by participant is provided in Listing 6.

Age Group: 18 to 55 Years

Participant demographics were generally similar across vaccination groups. The study population was generally balanced with respect to sex (Table 7). The majority of participants were White (53 [88%] participants) and not of Hispanic or Latino ethnicity (52 [87%] participants). The median age was 32.1 years (range: 18 to 54). The median BMI was 24.45 kg/m^2 (range: 18.5 to 32.6).

Age Group: 56 to 70 Years

Participant demographics were generally similar across vaccination groups. A total of 17 (57%) female participants and 13 (43%) male participants were enrolled in the study (Table 8). The majority of participants were White (27 [90%] participants). All 30 (100%) participants were not of Hispanic or Latino ethnicity. The median age was 65.0 years (range: 56 to 70). The median BMI was 23.45 kg/m^2 (range: 20.8 to 29.5).

Age Group: ≥ 71 Years

Participant demographics were generally similar across vaccination groups. A total of 13 (43%) female participants and 17 (57%) male participants were enrolled in the study (Table 9). The

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majority of participants were White (29 [97%] participants) and not of Hispanic or Latino ethnicity (28 [93%] participants). The median age was 72.9 years (range: 71 to 83 years). The median BMI was 25.35 kg/m^2 (range: 19.9 to 29.7).

Table 7: Summary of Participant Demographics (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
	25 µg (N=15)	**50 µg (N=15)**	**100 µg (N=15)**	**250 µg (N=15)**	**All Participants (N=60)**
Sex, n (%)					
Male	9 (60)	9 (60)	7 (47)	6 (40)	31 (52)
Female	6 (40)	6 (40)	8 (53)	9 (60)	29 (48)
Ethnicity, n (%)					
Not Hispanic or Latino	14 (93)	14 (93)	12 (80)	12 (80)	52 (87)
Hispanic or Latino	1 (7)	1 (7)	3 (20)	2 (13)	7 (12)
Not reported	–	–	–	1 (7)	1 (2)
Unknown	–	–	–	–	–
Race, n (%)					
American Indian or Alaska Native	–	–	1 (7)	–	1 (2)
Asian	–	2 (13)	–	1 (7)	3 (5)
Native Hawaiian or other Pacific Islander	–	–	–	–	–
Black	–	–	2 (13)	–	2 (3)
White	15 (100)	13 (87)	11 (73)	14 (93)	53 (88)
Multi-racial	–	–	–	–	–
Unknown	–	–	1 (7)	–	1 (2)
Age (years)					
Mean (SD)	36.7 (7.9)	37.0 (10.0)	31.3 (8.7)	31.0 (8.0)	34.0 (8.9)
Median	35.9	34.6	31.6	30.3	32.1
Min, Max	25, 53	22, 54	20, 53	18, 50	18, 54
BMI (kg/m^2)					
Mean (SD)	24.62 (3.45)	23.12 (3.16)	26.73 (2.60)	24.68 (3.09)	24.79 (3.28)
Median	24.50	22.60	27.40	23.70	24.45
Min, Max	21.1, 32.6	18.5, 30.3	20.4, 31.5	20.4, 29.4	18.5, 32.6

Abbreviations: BMI = body mass index; Max = maximum; Min = minimum.
Sources: Posttext Table 6 and Posttext Table 9.

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Table 8: Summary of Participant Demographics (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Sex, n (%)				
Male	3 (30)	5 (50)	5 (50)	13 (43)
Female	7 (70)	5 (50)	5 (50)	17 (57)
Ethnicity, n (%)				
Not Hispanic or Latino	10 (100)	10 (100)	10 (100)	30 (100)
Hispanic or Latino	–	–	–	–
Not reported	–	–	–	–
Unknown	–	–	–	–
Race, n (%)				
American Indian or Alaska Native	–	–	–	–
Asian	–	1 (10)	–	1 (3)
Native Hawaiian or other Pacific Islander	–	–	–	–
Black	–	1 (10)	–	1 (3)
White	10 (100)	7 (70)	10 (100)	27 (90)
Multi-racial	–	1 (10)	–	1 (3)
Unknown	–	–	–	–
Age (years)				
Mean (SD)	65.8 (4.5)	62.1 (3.7)	63.8 (4.3)	63.9 (4.3)
Median	67.0	61.6	64.5	65.0
Min, Max	56, 70	56, 68	56, 69	56, 70
BMI (kg/m^2)				
Mean (SD)	25.38 (2.53)	23.41 (2.02)	23.73 (2.26)	24.17 (2.37)
Median	24.85	23.25	23.80	23.45
Min, Max	22.4, 29.5	21.0, 27.8	20.8, 27.4	20.8, 29.5

Abbreviations: BMI = body mass index; Max = maximum; Min = minimum.
Sources: Posttext Table 7 and Posttext Table 10.

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Table 9: Summary of Participant Demographics (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Sex, n (%)				
Male	8 (80)	6 (60)	3 (30)	17 (57)
Female	2 (20)	4 (40)	7 (70)	13 (43)
Ethnicity, n (%)				
Not Hispanic or Latino	9 (90)	9 (90)	10 (100)	28 (93)
Hispanic or Latino	1 (10)	1 (10)	–	2 (7)
Not reported	–	–	–	–
Unknown	–	–	–	–
Race, n (%)				
American Indian or Alaska Native	–	–	–	–
Asian	1 (10)	–	–	1 (3)
Native Hawaiian or other Pacific Islander	–	–	–	–
Black	–	–	–	–
White	9 (90)	10 (100)	10 (100)	29 (97)
Multi-racial	–	–	–	–
Unknown	–	–	–	–
Age (years)				
Mean (SD)	72.8 (1.2)	75.1 (3.4)	72.6 (1.1)	73.5 (2.4)
Median	72.6	73.6	72.6	72.9
Min, Max	71, 75	72, 83	71, 75	71, 83
BMI (kg/m^2)				
Mean (SD)	24.76 (3.53)	24.66 (2.72)	26.02 (3.52)	25.15 (3.22)
Median	25.80	24.60	26.70	25.35
Min, Max	19.9, 29.2	20.7, 29.1	20.1, 29.7	19.9, 29.7

Abbreviations: BMI = body mass index; Max = maximum; Min = minimum.
Sources: Posttext Table 8 and Posttext Table 11.

5.4 Exposure and Compliance

Overall, 120 (100%) participants received the first injection and 116/120 (97%) participants received the second injection (Table 4, Table 5, and Table 6). One participant in the 25 µg vaccination group (age group: 18 to 55 years) did not receive the second injection due to potential COVID-19 exposure; 1 participant each in the 25 µg (age group: 18 to 55 years),

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250 µg (age group: 18 to 55 years), and 100 µg (age group: 56 to 70 years) vaccination groups did not receive the second injection due to an AE (Section 7.3.3.1; Listing 2). All other participants received both injections of vaccine as planned (Listing 1).

5.5 Pre-Existing and Concurrent Medical Conditions

Pre-existing and concurrent medical conditions by participant are provided in Listing 7.

5.6 Prior and Concurrent Medications

Prior and concurrent medications are provided by participant in Listing 17.

Age Group: 18 to 55 Years

Overall, 58 (97%) participants reported the use of at least 1 prior or concurrent medication. The most common prior or concurrent medications (> 25% of the participants overall) by WHO drug code Level 2 were anti-inflammatory and antirheumatic products (38 [63%] participants), vitamins (33 [55%] participants), analgesics (24 [40%] participants), and antihistamines for systemic use (19 [32%] participants) (Posttext Table 172).

Age Group: 56 to 70 Years

All participants (100%) reported the use of at least 1 prior or concurrent medication. The most common prior or concurrent medications (> 25% of the participants overall) by WHO drug code Level 2 were anti-inflammatory and antirheumatic products (20 [67%] participants), vitamins (16 [53%] participants), analgesics (12 [40%] participants), and antihistamines for systemic use (11 [37%] participants) (Posttext Table 173).

Age Group: ≥71 Years

All participants (100%) reported the use of at least 1 prior or concurrent medication. The most common prior or concurrent medications (> 25% of the participants overall) by WHO drug code Level 2 were vitamins (19 [63%] participants); anti-inflammatory and antirheumatic products (18 [60%] participants); analgesics (14 [47%] participants); drugs for acid-related disorders (13 [43%] participants); mineral supplements (11 [37%] participants); lipid-modifying agents (10 [33%] participants); vaccines, agents acting on the renin-angiotensin system, and nasal preparations (8 [27%] participants each) (Posttext Table 174).

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6 Efficacy Results

Not applicable.

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7 Safety Results

7.1 Solicited Adverse Reactions

Solicited AEs (ie, reactogenicity) were anticipated local and systemic AEs. Solicited AEs were collected from Days 1 through 8 (7 days post first dose) and Days 29 through 36 (7 days post second dose) using a memory aid. Systemic AEs included fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), arthralgia (captured in the memory aid as joint pain), nausea, feverishness (captured in the memory aid as chills), and fever. Local AEs included pain at injection site, erythema (captured in the memory aid as redness), and induration (captured in the memory aid as swelling/hardness).

For consistency across the mRNA-1273 program, these solicited AEs were referred to as solicited ARs when summarized in the results.

All solicited ARs were considered related to mRNA-1273.

7.1.1 Summary of All Solicited Adverse Reactions

Age Group: 18 to 55 Years

Solicited ARs within 7 days after vaccination were reported in 56 (93%) participants. Most of the solicited ARs after any dose (the first or second injection) were mild (16 [27%] participants) or moderate (34 [57%] participants) in severity. Severe solicited ARs were reported in 6 (10%) participants; more severe solicited ARs were reported in the 250 µg vaccination group (4 participants) than in the other groups (1 participant each in the 50 µg and 100 µg vaccination groups) (Table 10).

Most of the ARs after the first injection were mild in severity, whereas most of the ARs after the second injection were moderate in severity. In addition, the incidence of severe ARs was higher after the second injection than after the first injection.

Age Group: 56 to 70 Years

Solicited ARs within 7 days after vaccination were reported in 28 (93%) participants. Most of the solicited ARs after any dose (the first or second injection) were mild (14 [47%] participants) or moderate (12 [40%] participants) in severity. Severe solicited ARs were reported in 2 (7%) participants (1 each in the 25 µg and 50 µg vaccination groups); no severe ARs were reported in the 100 µg vaccination group (Table 11).

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More participants reported moderate ARs after the second injection than after the first injection and severe ARs were reported only after the second injection.

Age Group: ≥ 71 Years

Solicited ARs within 7 days after vaccination were reported in 28 (93%) participants. Most of the solicited ARs after any dose (the first or second injection) were mild (19 [63%] participants) or moderate (8 [27%] participants) in severity. A severe solicited AR was reported in 1 (3%) participant in the 100 µg vaccination group (Table 12).

In general, the incidence of solicited ARs after the first injection was similar to that after the second injection.

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Table 10: Number and Percentage of Participants Reporting Solicited Adverse Reactions (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
Dose Severity, n (%)	**25 µg (N=15)**	**50 µg (N=15)**	**100 µg (N=15)**	**250 µg (N=15)**	**All Participants (N=60)**
Any Symptom					
Dose 1					
None	5 (33)	–	1 (7)	–	6 (10)
Any severity	10 (67)	15 (100)	14 (93)	15 (100)	54 (90)
Mild	8 (53)	9 (60)	10 (67)	9 (60)	36 (60)
Moderate	2 (13)	6 (40)	3 (20)	5 (33)	16 (27)
Severe	–	–	1 (7)	1 (7)	2 (3)
Dose 2					
None	3 (23)	–	–	–	3 (5)
Any severity	10 (77)	15 (100)	15 (100)	14 (100)	54 (95)
Mild	7 (54)	7 (47)	3 (20)	1 (7)	18 (32)
Moderate	3 (23)	7 (47)	11 (73)	9 (64)	30 (53)
Severe	-	1 (7)	1 (7)	4 (29)	6 (11)
Any dose					
None	4 (27)	–	–	–	4 (7)
Any severity	11 (73)	15 (100)	15 (100)	15 (100)	56 (93)
Mild	6 (40)	6 (40)	3 (20)	1 (7)	16 (27)
Moderate	5 (33)	8 (53)	11 (73)	10 (67)	34 (57)
Severe	–	1 (7)	1 (7)	4 (27)	6 (10)

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

Source: Posttext Table 75.

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Table 11: Number and Percentage of Participants Reporting Solicited Adverse Reactions (All Participants 56 to 70 Years of Age)

Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any Symptom				
Dose 1				
None	3 (30)	4 (40)	1 (10)	8 (27)
Any severity	7 (70)	6 (60)	9 (90)	22 (73)
Mild	5 (50)	4 (40)	9 (90)	18 (60)
Moderate	2 (20)	2 (20)	–	4 (13)
Severe	–	–	–	–
Dose 2				
None	–	2 (20)	1 (11)	3 (10)
Any severity	10 (100)	8 (80)	8 (89)	26 (90)
Mild	6 (60)	7 (70)	3 (33)	16 (55)
Moderate	3 (30)	–	5 (56)	8 (28)
Severe	1 (10)	1 (10)	–	2 (7)
Any dose				
None	–	1 (10)	1 (10)	2 (7)
Any severity	10 (100)	9 (90)	9 (90)	28 (93)
Mild	4 (40)	6 (60)	4 (40)	14 (47)
Moderate	5 (50)	2 (20)	5 (50)	12 (40)
Severe	1 (10)	1 (10)	–	2 (7)

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

Source: Posttext Table 78.

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Table 12: Number and Percentage of Participants Reporting Solicited Adverse Reactions (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
Dose Severity, n (%)	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Any Symptom				
Dose 1				
None	1 (10)	2 (20)	2 (20)	5 (17)
Any severity	9 (90)	8 (80)	8 (80)	25 (83)
Mild	9 (90)	7 (70)	8 (80)	24 (80)
Moderate	–	1 (10)	–	1 (3)
Severe	–	–	–	–
Dose 2				
None	1 (10)	3 (30)	–	4 (13)
Any severity	9 (90)	7 (70)	10 (100)	26 (87)
Mild	7 (70)	6 (60)	5 (50)	18 (60)
Moderate	2 (20)	1 (10)	4 (40)	7 (23)
Severe	–	–	1 (10)	1 (3)
Any dose				
None	–	2 (20)	–	2 (7)
Any severity	10 (100)	8 (80)	10 (100)	28 (93)
Mild	8 (80)	6 (60)	5 (50)	19 (63)
Moderate	2 (20)	2 (20)	4 (40)	8 (27)
Severe	–	–	1 (10)	1 (3)

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.
Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.
Source: Posttext Table 81.

7.1.2 Summary of Solicited Systemic Adverse Reactions

Solicited systemic AEs were collected using a memory aid. Systemic AEs included fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), arthralgia (captured in the memory aid as joint pain), nausea, feverishness (captured in the memory aid as chills), and fever.

For consistency across the mRNA-1273 program, solicited AEs were referred to as solicited ARs when summarized in the results.

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A trend for decreased frequency and severity of solicited systemic ARs in the older age groups was noted.

Age Group: 18 to 55 Years

Overall, 51 (85%) participants reported at least 1 solicited systemic AR within 7 days after vaccination: 8 (53%), 13 (87%), 15 (100%), and 15 (100%) participants in the 25 µg, 50 µg, 100 µg, and 250 µg vaccination groups, respectively. The majority of the solicited systemic ARs after any dose (the first or second injection) were mild (15 [25%] participants) or moderate (32 [53%] participants) in severity. Severe solicited systemic ARs were reported in 4 (7%) participants (Table 13).

The incidence of solicited systemic ARs regardless of severity was higher after the second injection (49 [86%] participants) than after the first injection (32 [53%] participants). The incidence of mild solicited systemic ARs was higher after the first injection (21 [35%] participants) than after the second injection (15 [26%] participants), whereas the incidence of moderate solicited systemic ARs was higher after the second injection (30 [53%] participants) than after the first injection (11 [18%] participants). No participant reported a severe solicited systemic AR after the first injection, and 4 (7%) participants reported a severe solicited systemic AR after the second injection. Overall, these results indicate that incidence of solicited systemic ARs increased after the second injection.

The most commonly reported (> 25% of the participants overall) solicited systemic ARs after any dose (the first or second injection) regardless of severity were fatigue, headache, myalgia, and feverishness. The most commonly reported (> 25% of the participants overall) solicited systemic ARs after the first injection regardless of severity were fatigue and headache. The most commonly reported (> 25% of the participants overall) solicited systemic ARs after the second injection regardless of severity were fatigue, headache, myalgia, feverishness, and fever. Notably, the incidence of arthralgia, feverishness, headache, myalgia, and nausea increased by more than 2-fold after the second injection compared with the incidence after the first injection. In addition, no participant reported fever after the first injection, but 15 (26%) participants reported fever after the second injection (Table 13).

Three participants in the 250 µg vaccination group reported severe solicited systemic ARs (all after the second injection): feverishness on Day 1 and fever (body temperature 39.6ºC), feverishness, fatigue, and headache on Day 2 in 1 participant; feverishness and fatigue on Day 2 in 1 participant; and feverishness, myalgia, and nausea on Day 2 in 1 participant. One

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participant in the 50 µg vaccination group reported severe headache on Day 2 after the second injection (Listing 10).

A trend for a dose-dependent increase in the incidence of fever, feverishness, headache, and myalgia was noted.

Age Group: 56 to 70 Years

Overall, 22 (73%) participants reported at least 1 solicited systemic AR within 7 days after vaccination: 8 (80%), 6 (60%), and 8 (80%) participants in the 25 µg, 50 µg, and 100 µg vaccination groups, respectively. Solicited systemic ARs after any dose (the first or second injection) were mild (11 [37%] participants) or moderate (10 [33%] participants) in severity except 1 (3%) participant with a severe AR (Table 14).

The incidence of solicited systemic ARs was higher after the second injection (20 [69%] participants) than after the first injection (11 [37%] participants). The incidence of mild and moderate solicited systemic ARs was higher after the second injection (12 [41%] and 7 [24%] participants, respectively) than after the first injection (8 [27%] and 3 [10%] participants, respectively). No participant reported a severe solicited systemic AR after the first injection, and 1 (3%) participant in the 25 µg vaccination group reported a severe solicited systemic AR of fever (body temperature 39.2ºC) on Day 2 after the second injection (Listing 10). Overall, these results indicate that incidence of solicited systemic ARs increased after the second injection.

The most commonly reported (> 25% of the participants overall) solicited systemic ARs after any dose (the first or second injection) regardless of severity were fatigue, myalgia, headache, feverishness, and nausea. The incidence of any individual solicited systemic AR after the first injection was low (0 to 20%). The most commonly reported (> 25% of the participants overall) solicited systemic ARs after the second injection regardless of severity were fatigue, myalgia, headache, and feverishness. Notably, no participants reported feverishness after the first injection, but 9 (31%) participants reported mild and moderate feverishness after the second injection (Table 14).

In general, no clinically relevant dose-dependent trends in the incidence of solicited systemic ARs were noted among the vaccination groups.

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Age Group: ≥ 71 Years

Overall, 18 (60%) participants reported at least 1 solicited systemic AR within 7 days after vaccination: 5 (50%), 6 (60%), and 7 (70%) participants in the 25 µg, 50 µg, and 100 µg vaccination groups, respectively. Solicited systemic ARs after any dose (the first or second injection) were mild (12 [40%] participants) or moderate (5 [17%] participants) in severity, except for 1 (3%) participant with a severe AR (Table 15).

The incidence of solicited systemic ARs was higher after the second injection (16 [53%] participants) than after the first injection (12 [40%] participants). The incidences of mild and moderate solicited systemic ARs after the first injection were similar to those after the second injection. No participant reported a severe solicited systemic AR after the first injection, and 1 (3%) participant in the 100 µg vaccination group reported a severe solicited systemic AR of fatigue on Day 2 after the second injection (Listing 10).

The most commonly reported (> 25% of the participants overall) solicited systemic ARs after any dose regardless of severity were fatigue, myalgia, and headache. The most commonly reported (> 25% of the participants overall) solicited systemic AR after the first injection regardless of severity was fatigue. The most commonly reported (> 25% of the participants overall) solicited systemic ARs after the second injection regardless of severity were fatigue and myalgia.

A trend for a dose-dependent increase in the incidence of fatigue, particularly after the second injection, was noted.

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Table 13: Number and Percentage of Participants Reporting Solicited Systemic Adverse Reactions (All Participants 18 to 55 Years of Age)

Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Any Systemic Symptom,					
Dose 1					
None	10 (67)	6 (40)	5 (33)	7 (47)	28 (47)
Any severity	5 (33)	9 (60)	10 (67)	8 (53)	32 (53)
Mild	3 (20)	6 (40)	8 (53)	4 (27)	21 (35)
Moderate	2 (13)	3 (20)	2 (13)	4 (27)	11 (18)
Severe	–	–	–	–	–
Dose 2					
None	6 (46)	2 (13)	–	–	8 (14)
Any severity	7 (54)	13 (87)	15 (100)	14 (100)	49 (86)
Mild	4 (31)	6 (40)	3 (20)	2 (14)	15 (26)
Moderate	3 (23)	6 (40)	12 (80)	9 (64)	30 (53)
Severe	–	1 (7)	-	3 (21)	4 (7)
Any dose					
None	7 (47)	2 (13)	–	–	9 (15)
Any severity	8 (53)	13 (87)	15 (100)	15 (100)	51 (85)
Mild	3 (20)	6 (40)	3 (20)	3 (20)	15 (25)
Moderate	5 (33)	6 (40)	12 (80)	9 (60)	32 (53)
Severe	–	1 (7)	–	3 (20)	4 (7)
Arthralgia					
Dose 1					
None	15 (100)	13 (87)	13 (87)	14 (93)	55 (92)
Any severity	–	2 (13)	2 (13)	1 (7)	5 (8)
Mild	–	2 (13)	1 (7)	1 (7)	4 (7)
Moderate	–	–	1 (7)	–	1 (2)
Severe	–	–	–	–	–
Dose 2					
None	11 (85)	13 (87)	13 (87)	6 (43)	43 (75)
Any severity	2 (15)	2 (13)	2 (13)	8 (57)	14 (25)
Mild	–	1 (7)	1 (7)	5 (36)	7 (12)
Moderate	2 (15)	1 (7)	1 (7)	3 (21)	7 (12)
Severe	–	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Any dose					
None	13 (87)	12 (80)	13 (87)	7 (47)	45 (75)
Any severity	2 (13)	3 (20)	2 (13)	8 (53)	15 (25)
Mild	–	2 (13)	–	5 (33)	7 (12)
Moderate	2 (13)	1 (7)	2 (13)	3 (20)	8 (13)
Severe	–	–	–	–	–
Fatigue					
Dose 1					
None	11 (73)	7 (47)	11 (73)	10 (67)	39 (65)
Any severity	4 (27)	8 (53)	4 (27)	5 (33)	21 (35)
Mild	2 (13)	5 (33)	3 (20)	3 (20)	13 (22)
Moderate	2 (13)	3 (20)	1 (7)	2 (13)	8 (13)
Severe	–	–	–	–	–
Dose 2					
None	8 (62)	5 (33)	3 (20)	4 (29)	20 (35)
Any severity	5 (38)	10 (67)	12 (80)	10 (71)	37 (65)
Mild	4 (31)	4 (27)	6 (40)	2 (14)	16 (28)
Moderate	1 (8)	6 (40)	6 (40)	6 (43)	19 (33)
Severe	–	–	–	2 (14)	2 (4)
Any dose					
None	8 (53)	5 (33)	3 (20)	5 (33)	21 (35)
Any severity	7 (47)	10 (67)	12 (80)	10 (67)	39 (65)
Mild	4 (27)	4 (27)	5 (33)	2 (13)	15 (25)
Moderate	3 (20)	6 (40)	7 (47)	6 (40)	22 (37)
Severe	–	–	–	2 (13)	2 (3)
Fever[a]					
Dose 1					
None	15 (100)	15 (100)	15 (100)	15 (100)	60 (100)
Any severity	–	–	–	–	–
Mild	–	–	–	–	–
Moderate	–	–	–	–	–
Severe	–	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Dose 2					
None	13 (100)	14 (93)	9 (60)	6 (43)	42 (74)
Any severity	–	1 (7)	6 (40)	8 (57)	15 (26)
Mild	–	1 (7)	5 (33)	5 (36)	11 (19)
Moderate	–	–	1 (7)	2 (14)	3 (5)
Severe	–	–	–	1 (7)	1 (2)
Any dose					
None	15 (100)	14 (93)	9 (60)	7 (47)	45 (75)
Any severity	–	1 (7)	6 (40)	8 (53)	15 (25)
Mild	–	1 (7)	5 (33)	5 (33)	11 (18)
Moderate	–	–	1 (7)	2 (13)	3 (5)
Severe	–	–	–	1 (7)	1 (2)
Feverishness					
Dose 1					
None	15 (100)	15 (100)	14 (93)	13 (87)	57 (95)
Any severity	–	–	1 (7)	2 (13)	3 (5)
Mild	–	–	1 (7)	2 (13)	3 (5)
Moderate	–	–	–	–	–
Severe	–	–	–	–	–
Dose 2					
None	12 (92)	12 (80)	3 (20)	2 (14)	29 (51)
Any severity	1 (8)	3 (20)	12 (80)	12 (86)	28 (49)
Mild	1 (8)	2 (13)	8 (53)	4 (29)	15 (26)
Moderate	–	1 (7)	4 (27)	5 (36)	10 (18)
Severe	–	–	–	3 (21)	3 (5)
Any dose					
None	14 (93)	12 (80)	3 (20)	3 (20)	32 (53)
Any severity	1 (7)	3 (20)	12 (80)	12 (80)	28 (47)
Mild	1 (7)	2 (13)	8 (53)	4 (27)	15 (25)
Moderate	–	1 (7)	4 (27)	5 (33)	10 (17)
Severe	–	–	–	3 (20)	3 (5)

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Headache					
Dose 1					
None	12 (80)	12 (80)	11 (73)	8 (53)	43 (72)
Any severity	3 (20)	3 (20)	4 (27)	7 (47)	17 (28)
Mild	3 (20)	3 (20)	4 (27)	4 (27)	14 (23)
Moderate	–	–	–	3 (20)	3 (5)
Severe	–	–	–	–	–
Dose 2					
None	10 (77)	5 (33)	6 (40)	–	21 (37)
Any severity	3 (23)	10 (67)	9 (60)	14 (100)	36 (63)
Mild	2 (15)	6 (40)	5 (33)	9 (64)	22 (39)
Moderate	1 (8)	3 (20)	4 (27)	4 (29)	12 (21)
Severe	–	1 (7)	–	1 (7)	2 (4)
Any dose					
None	11 (73)	5 (33)	5 (33)	–	21 (35)
Any severity	4 (27)	10 (67)	10 (67)	15 (100)	39 (65)
Mild	3 (20)	6 (40)	6 (40)	9 (60)	24 (40)
Moderate	1 (7)	3 (20)	4 (27)	5 (33)	13 (22)
Severe	–	1 (7)	–	1 (7)	2 (3)
Myalgia					
Dose 1					
None	14 (93)	13 (87)	14 (93)	11 (73)	52 (87)
Any severity	1 (7)	2 (13)	1 (7)	4 (27)	8 (13)
Mild	1 (7)	2 (13)	1 (7)	4 (27)	8 (13)
Moderate	–	–	–	–	–
Severe	–	–	–	–	–
Dose 2					
None	10 (77)	9 (60)	7 (47)	1 (7)	27 (47)
Any severity	3 (23)	6 (40)	8 (53)	13 (93)	30 (53)
Mild	2 (15)	2 (13)	2 (13)	5 (36)	11 (19)
Moderate	1 (8)	4 (27)	6 (40)	7 (50)	18 (32)
Severe	–	–	–	1 (7)	1 (2)

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Any dose					
None	11 (73)	9 (60)	7 (47)	2 (13)	29 (48)
Any severity	4 (27)	6 (40)	8 (53)	13 (87)	31 (52)
Mild	3 (20)	2 (13)	2 (13)	5 (33)	12 (20)
Moderate	1 (7)	4 (27)	6 (40)	7 (47)	18 (30)
Severe	–	–	–	1 (7)	1 (2)
Nausea					
Dose 1					
None	14 (93)	14 (93)	15 (100)	14 (93)	57 (95)
Any severity	1 (7)	1 (7)	–	1 (7)	3 (5)
Mild	–	–	–	1 (7)	1 (2)
Moderate	1 (7)	1 (7)	–	–	2 (3)
Severe	–	–	–	–	–
Dose 2					
None	12 (92)	13 (87)	8 (53)	10 (71)	43 (75)
Any severity	1 (8)	2 (13)	7 (47)	4 (29)	14 (25)
Mild	1 (8)	2 (13)	6 (40)	1 (7)	10 (18)
Moderate	–	–	1 (7)	2 (14)	3 (5)
Severe	–	–	–	1 (7)	1 (2)
Any dose					
None	13 (87)	13 (87)	8 (53)	11 (73)	45 (75)
Any severity	2 (13)	2 (13)	7 (47)	4 (27)	15 (25)
Mild	1 (7)	1 (7)	6 (40)	1 (7)	9 (15)
Moderate	1 (7)	1 (7)	1 (7)	2 (13)	5 (8)
Severe	–	–	–	1 (7)	1 (2)

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

The following symptoms reported by the participant were mapped to the database as follows: chills = feverishness; tiredness = fatigue; body aches/muscle pain = myalgia; joint pain = arthralgia.

[a] Fever percentages reflect the number of participants with at least 1 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.

Source: Posttext Table 76.

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Table 14: Number and Percentage of Participants Reporting Solicited Systemic Adverse Reactions (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
Dose Severity, n (%)	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Any Systemic Symptom				
Dose 1				
None	5 (50)	7 (70)	7 (70)	19 (63)
Any severity	5 (50)	3 (30)	3 (30)	11 (37)
Mild	3 (30)	2 (20)	3 (30)	8 (27)
Moderate	2 (20)	1 (10)	–	3 (10)
Severe	–	–	–	–
Dose 2				
None	3 (30)	5 (50)	1 (11)	9 (31)
Any severity	7 (70)	5 (50)	8 (89)	20 (69)
Mild	5 (50)	4 (40)	3 (33)	12 (41)
Moderate	1 (10)	1 (10)	5 (56)	7 (24)
Severe	1 (10)	–	–	1 (3)
Any dose				
None	2 (20)	4 (40)	2 (20)	8 (27)
Any severity	8 (80)	6 (60)	8 (80)	22 (73)
Mild	4 (40)	4 (40)	3 (30)	11 (37)
Moderate	3 (30)	2 (20)	5 (50)	10 (33)
Severe	1 (10)	–	–	1 (3)
Arthralgia				
Dose 1				
None	7 (70)	10 (100)	10 (100)	27 (90)
Any severity	3 (30)	–	–	3 (10)
Mild	1 (10)	–	–	1 (3)
Moderate	2 (20)	–	–	2 (7)
Severe	–	–	–	–
Dose 2				
None	9 (90)	9 (90)	7 (78)	25 (86)
Any severity	1 (10)	1 (10)	2 (22)	4 (14)
Mild	–	1 (10)	1 (11)	2 (7)
Moderate	1 (10)	–	1 (11)	2 (7)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	6 (60)	9 (90)	8 (80)	23 (77)
Any severity	4 (40)	1 (10)	2 (20)	7 (23)
Mild	1 (10)	1 (10)	1 (10)	3 (10)
Moderate	3 (30)	–	1 (10)	4 (13)
Severe	–	–	–	–
Fatigue				
Dose 1				
None	8 (80)	9 (90)	7 (70)	24 (80)
Any severity	2 (20)	1 (10)	3 (30)	6 (20)
Mild	2 (20)	1 (10)	3 (30)	6 (20)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	6 (60)	5 (50)	2 (22)	13 (45)
Any severity	4 (40)	5 (50)	7 (78)	16 (55)
Mild	2 (20)	4 (40)	2 (22)	8 (28)
Moderate	2 (20)	1 (10)	5 (56)	8 (28)
Severe	–	–	–	–
Any dose				
None	6 (60)	5 (50)	3 (30)	14 (47)
Any severity	4 (40)	5 (50)	7 (70)	16 (53)
Mild	2 (20)	4 (40)	2 (20)	8 (27)
Moderate	2 (20)	1 (10)	5 (50)	8 (27)
Severe	–	–	–	–
Fever[a]				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Dose 2				
None	9 (90)	9 (90)	8 (89)	26 (90)
Any severity	1 (10)	1 (10)	1 (11)	3 (10)
Mild	–	1 (10)	1 (11)	2 (7)
Moderate	–	–	–	–
Severe	1 (10)	–	–	1 (3)
Any dose				
None	9 (90)	9 (90)	9 (90)	27 (90)
Any severity	1 (10)	1 (10)	1 (10)	3 (10)
Mild	–	1 (10)	1 (10)	2 (7)
Moderate	–	–	–	–
Severe	1 (10)	–	–	1 (3)
Feverishness				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	8 (80)	8 (80)	4 (44)	20 (69)
Any severity	2 (20)	2 (20)	5 (56)	9 (31)
Mild	1 (10)	1 (10)	3 (33)	5 (17)
Moderate	1 (10)	1 (10)	2 (22)	4 (14)
Severe	–	–	–	–
Any dose				
None	8 (80)	8 (80)	5 (50)	21 (70)
Any severity	2 (20)	2 (20)	5 (50)	9 (30)
Mild	1 (10)	1 (10)	3 (30)	5 (17)
Moderate	1 (10)	1 (10)	2 (20)	4 (13)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Headache				
Dose 1				
None	8 (80)	9 (90)	10 (100)	27 (90)
Any severity	2 (20)	1 (10)	–	3 (10)
Mild	2 (20)	1 (10)	–	3 (10)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	7 (70)	7 (70)	2 (22)	16 (55)
Any severity	3 (30)	3 (30)	7 (78)	13 (45)
Mild	2 (20)	3 (30)	6 (67)	11 (38)
Moderate	1 (10)	–	1 (11)	2 (7)
Severe	–	–	–	–
Any dose				
None	6 (60)	7 (70)	3 (30)	16 (53)
Any severity	4 (40)	3 (30)	7 (70)	14 (47)
Mild	3 (30)	3 (30)	6 (60)	12 (40)
Moderate	1 (10)	–	1 (10)	2 (7)
Severe	–	–	–	–
Myalgia				
Dose 1				
None	8 (80)	9 (90)	9 (90)	26 (87)
Any severity	2 (20)	1 (10)	1 (10)	4 (13)
Mild	2 (20)	1 (10)	1 (10)	4 (13)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	4 (40)	8 (80)	2 (22)	14 (48)
Any severity	6 (60)	2 (20)	7 (78)	15 (52)
Mild	5 (50)	2 (20)	3 (33)	10 (34)
Moderate	1 (10)	–	4 (44)	5 (17)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	4 (40)	7 (70)	3 (30)	14 (47)
Any severity	6 (60)	3 (30)	7 (70)	16 (53)
Mild	5 (50)	3 (30)	3 (30)	11 (37)
Moderate	1 (10)	–	4 (40)	5 (17)
Severe	–	–	–	–
Nausea				
Dose 1				
None	10 (100)	8 (80)	10 (100)	28 (93)
Any severity	–	2 (20)	–	2 (7)
Mild	–	1 (10)	–	1 (3)
Moderate	–	1 (10)	–	1 (3)
Severe	–	–	–	–
Dose 2				
None	8 (80)	10 (100)	5 (56)	23 (79)
Any severity	2 (20)	–	4 (44)	6 (21)
Mild	2 (20)	–	2 (22)	4 (14)
Moderate	–	–	2 (22)	2 (7)
Severe	–	–	–	–
Any dose				
None	8 (80)	8 (80)	6 (60)	22 (73)
Any severity	2 (20)	2 (20)	4 (40)	8 (27)
Mild	2 (20)	1 (10)	2 (20)	5 (17)
Moderate	–	1 (10)	2 (20)	3 (10)
Severe	–	–	–	–

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

The following symptoms reported by the participant were mapped to the database as follows: chills = feverishness; tiredness = fatigue; body aches/muscle pain = myalgia; joint pain = arthralgia.

[a] Fever percentages reflect the number of participants with at least 1 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.

Source: Posttext Table 79.

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Table 15: Number and Percentage of Participants Reporting Solicited Systemic Adverse Reactions (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
Dose Severity, n (%)	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Any Systemic Symptom				
Dose 1				
None	5 (50)	6 (60)	7 (70)	18 (60)
Any severity	5 (50)	4 (40)	3 (30)	12 (40)
Mild	5 (50)	3 (30)	3 (30)	11 (37)
Moderate	–	1 (10)	–	1 (3)
Severe	–	–	–	–
Dose 2				
None	7 (70)	4 (40)	3 (30)	14 (47)
Any severity	3 (30)	6 (60)	7 (70)	16 (53)
Mild	3 (30)	5 (50)	3 (30)	11 (37)
Moderate	–	1 (10)	3 (30)	4 (13)
Severe	–	–	1 (10)	1 (3)
Any dose				
None	5 (50)	4 (40)	3 (30)	12 (40)
Any severity	5 (50)	6 (60)	7 (70)	18 (60)
Mild	5 (50)	4 (40)	3 (30)	12 (40)
Moderate	–	2 (20)	3 (30)	5 (17)
Severe	–	–	1 (10)	1 (3)
Arthralgia				
Dose 1				
None	9 (90)	9 (90)	10 (100)	28 (93)
Any severity	1 (10)	1 (10)	–	2 (7)
Mild	1 (10)	1 (10)	–	2 (7)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	10 (100)	10 (100)	8 (80)	28 (93)
Any severity	–	–	2 (20)	2 (7)
Mild	–	–	2 (20)	2 (7)
Moderate	–	–	–	–
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	9 (90)	9 (90)	8 (80)	26 (87)
Any severity	1 (10)	1 (10)	2 (20)	4 (13)
Mild	1 (10)	1 (10)	2 (20)	4 (13)
Moderate	–	–	–	–
Severe	–	–	–	–
Fatigue				
Dose 1				
None	8 (80)	6 (60)	7 (70)	21 (70)
Any severity	2 (20)	4 (40)	3 (30)	9 (30)
Mild	2 (20)	3 (30)	3 (30)	8 (27)
Moderate	–	1 (10)	–	1 (3)
Severe	–	–	–	–
Dose 2				
None	9 (90)	5 (50)	3 (30)	17 (57)
Any severity	1 (10)	5 (50)	7 (70)	13 (43)
Mild	1 (10)	4 (40)	3 (30)	8 (27)
Moderate	–	1 (10)	3 (30)	4 (13)
Severe	–	–	1 (10)	1 (3)
Any dose				
None	7 (70)	5 (50)	3 (30)	15 (50)
Any severity	3 (30)	5 (50)	7 (70)	15 (50)
Mild	3 (30)	3 (30)	3 (30)	9 (30)
Moderate	–	2 (20)	3 (30)	5 (17)
Severe	–	–	1 (10)	1 (3)
Fever[a]				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Dose 2				
None	10 (100)	10 (100)	9 (90)	29 (97)
Any severity	–	–	1 (10)	1 (3)
Mild	–	–	1 (10)	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–
Any dose				
None	10 (100)	10 (100)	9 (90)	29 (97)
Any severity	–	–	1 (10)	1 (3)
Mild	–	–	1 (10)	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–
Feverishness				
Dose 1				
None	10 (100)	10 (100)	9 (90)	29 (97)
Any severity	–	–	1 (10)	1 (3)
Mild	–	–	1 (10)	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	10 (100)	10 (100)	6 (60)	26 (87)
Any severity	–	–	4 (40)	4 (13)
Mild	–	–	3 (30)	3 (10)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–
Any dose				
None	10 (100)	10 (100)	5 (50)	25 (83)
Any severity	–	–	5 (50)	5 (17)
Mild	–	–	4 (40)	4 (13)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Headache				
Dose 1				
None	7 (70)	9 (90)	10 (100)	26 (87)
Any severity	3 (30)	1 (10)	–	4 (13)
Mild	3 (30)	1 (10)	–	4 (13)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	8 (80)	10 (100)	6 (60)	24 (80)
Any severity	2 (20)	–	4 (40)	6 (20)
Mild	2 (20)	–	3 (30)	5 (17)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–
Any dose				
None	6 (60)	9 (90)	6 (60)	21 (70)
Any severity	4 (40)	1 (10)	4 (40)	9 (30)
Mild	4 (40)	1 (10)	3 (30)	8 (27)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–
Myalgia				
Dose 1				
None	7 (70)	10 (100)	8 (80)	25 (83)
Any severity	3 (30)	–	2 (20)	5 (17)
Mild	3 (30)	–	2 (20)	5 (17)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	9 (90)	8 (80)	4 (40)	21 (70)
Any severity	1 (10)	2 (20)	6 (60)	9 (30)
Mild	1 (10)	2 (20)	5 (50)	8 (27)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	7 (70)	8 (80)	4 (40)	19 (63)
Any severity	3 (30)	2 (20)	6 (60)	11 (37)
Mild	3 (30)	2 (20)	5 (50)	10 (33)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–
Nausea				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	10 (100)	10 (100)	9 (90)	29 (97)
Any severity	–	–	1 (10)	1 (3)
Mild	–	–	1 (10)	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–
Any dose				
None	10 (100)	10 (100)	9 (90)	29 (97)
Any severity	–	–	1 (10)	1 (3)
Mild	–	–	1 (10)	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

The following symptoms reported by the participant were mapped to the database as follows: chills = feverishness; tiredness = fatigue; body aches/muscle pain = myalgia; joint pain = arthralgia.

[a] Fever percentages reflect the number of participants with at least 1 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.

Source: Posttext Table 82.

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7.1.3 Summary of Solicited Local Adverse Reactions

Solicited local AEs were collected using a memory aid. Local AEs included pain at injection site, erythema (captured in the memory aid as redness), and induration (captured in the memory aid as swelling/hardness).

For consistency across the mRNA-1273 program, these solicited AEs were referred to as solicited ARs when summarized in the results.

Age Group: 18 to 55 Years

Overall, 55 (92%) participants reported at least 1 solicited local AR within 7 days after vaccination: 11 (73%), 14 (93%), 15 (100%), and 15 (100%) participants in the 25 µg, 50 µg, 100 µg, and 250 µg vaccination groups, respectively. The majority of the solicited local ARs after any dose (the first or second injection) were mild (35 [58%] participants) or moderate (18 [30%] participants) in severity. Severe solicited local ARs were reported in 2 (3%) participants (Table 16).

The incidence of solicited local ARs after the first injection (52 [87%] participants) was similar to that after the second injection (53 [93%] participants). The incidences of mild, moderate, and severe solicited local ARs after the first injection (40 [67%], 10 [17%], and 2 [3%] participants, respectively) were similar to those after the second injection (37 [65%], 14 [25%], and 2 [4%] participants, respectively).

Pain was the only solicited local AR that was reported in > 25% of the participants overall (ie, the most common AR) after any dose. All ARs of pain were mild or moderate in severity.

Severe solicited local ARs were reported by 2 participants, and both participants reported a severe AR after each dose. The 2 participants (1 each in the 100 µg and 250 µg vaccination groups) reported severe erythema/redness measurement on Day 3 after the second injection. Both participants also reported severe erythema/redness measurement on Day 12 after the first injection, and the participant in the 250 µg vaccination group also reported severe induration/swelling measurement on Day 12 after the first injection (Listing 11).

In general, the incidence of solicited local ARs was similar after the first injection and the second injection. No clinically relevant dose-dependent trends were noted in the incidence of solicited local ARs among the vaccination groups.

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Age Group: 56 to 70 Years

Overall, 26 (87%) participants reported at least 1 solicited local AR within 7 days after vaccination: 8 (80%), 9 (90%), and 9 (90%) participants in the 25 µg, 50 µg, and 100 µg vaccination groups, respectively. Solicited local ARs after any dose (the first or second injection) were mild (19 [63%] participants) or moderate (6 [20%] participants) in severity except for 1 (3%) participant with severe ARs (Table 17).

The incidence of solicited local ARs after the first injection (19 [63%] participants) was similar to that after the second injection (22 [76%] participants). The incidences of mild and moderate solicited local ARs after the first injection (17 [57%] and 2 [7%] participants, respectively) were similar to those after the second injection (17 [59%] and 4 [14%] participants, respectively). One participant in the 50 µg vaccination group reported severe erythema/redness and erythema/redness measurement on Day 3 after the second injection (Listing 11).

The most commonly reported (> 25% of the participants overall) solicited local ARs after any dose regardless of severity were pain and induration/swelling; pain was the most commonly reported AR after the first and second injections. All ARs of pain were mild or moderate in severity.

In general, the incidence of solicited local ARs was similar after the first injection and the second injection. No clinically relevant dose-dependent trends were noted in the incidence of solicited local ARs among the vaccination groups.

Age Group: ≥ 71 Years

Overall, 25 (83%) participants reported at least 1 solicited local AR within 7 days after vaccination: 8 (80%), 7 (70%), and 10 (100%) participants in the 25 µg, 50 µg, and 100 µg vaccination groups, respectively. All solicited local ARs after any dose (the first or second injection) were mild (19 [63%] participants) or moderate (6 [20%] participants) in severity (Table 18).

The incidence of solicited local ARs after the first injection (21 [70%] participants) was the same as that after the second injection (21 [70%] participants). The incidence of mild solicited local ARs was higher after the first injection (21 [70%] participants) than after the second injection (15 [20%] participants). No participants reported a moderate solicited local AR after the first injection, whereas 6 (20%) participants reported a moderate solicited local AR after the second injection.

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The most commonly reported (> 25% of the participants overall) solicited local ARs after any dose regardless of severity were pain and erythema/redness; pain was the most commonly reported AR after the first and second injections.

In general, the incidence of solicited local ARs was similar after the first injection and the second injection. No clinically relevant dose-dependent trends were noted in the incidence of solicited local ARs among the vaccination groups.

Table 16: Number and Percentage of Participants Reporting Solicited Local Adverse Reactions (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
Dose Severity, n (%)	**25 µg (N=15)**	**50 µg (N=15)**	**100 µg (N=15)**	**250 µg (N=15)**	**All Participants (N=60)**
Any Local Symptom					
Dose 1					
None	5 (33)	2 (13)	1 (7)	–	8 (13)
Any severity	10 (67)	13 (87)	14 (93)	15 (100)	52 (87)
Mild	10 (67)	10 (67)	11 (73)	9 (60)	40 (67)
Moderate	–	3 (20)	2 (13)	5 (33)	10 (17)
Severe	–	–	1 (7)	1 (7)	2 (3)
Dose 2					
None	3 (23)	1 (7)	–	–	4 (7)
Any severity	10 (77)	14 (93)	15 (100)	14 (100)	53 (93)
Mild	9 (69)	11 (73)	10 (67)	7 (50)	37 (65)
Moderate	1 (8)	3 (20)	4 (27)	6 (43)	14 (25)
Severe	–	–	1 (7)	1 (7)	2 (4)
Any dose					
None	4 (27)	1 (7)	–	–	5 (8)
Any severity	11 (73)	14 (93)	15 (100)	15 (100)	55 (92)
Mild	10 (67)	10 (67)	9 (60)	6 (40)	35 (58)
Moderate	1 (7)	4 (27)	5 (33)	8 (53)	18 (30)
Severe	–	–	1 (7)	1 (7)	2 (3)

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Erythema/Redness					
Dose 1					
None	15 (100)	14 (93)	13 (87)	13 (87)	55 (92)
Any severity	–	1 (7)	2 (13)	2 (13)	5 (8)
Mild	–	1 (7)	2 (13)	2 (13)	5 (8)
Moderate	–	–	–	–	–
Severe	–	–	–	–	–
Dose 2					
None	12 (92)	11 (73)	13 (87)	11 (79)	47 (82)
Any severity	1 (8)	4 (27)	2 (13)	3 (21)	10 (18)
Mild	1 (8)	4 (27)	2 (13)	3 (21)	10 (18)
Moderate	–	–	–	–	–
Severe	–	–	–	–	–
Any dose					
None	14 (93)	11 (73)	13 (87)	11 (73)	49 (82)
Any severity	1 (7)	4 (27)	2 (13)	4 (27)	11 (18)
Mild	1 (7)	4 (27)	2 (13)	4 (27)	11 (18)
Moderate	–	–	–	–	–
Severe	–	–	–	–	–
Erythema/Redness Measurement (mm)					
Dose 1					
None	15 (100)	15 (100)	13 (87)	14 (93)	57 (95)
Any severity	–	–	2 (13)	1 (7)	3 (5)
Mild	–	–	–	–	–
Moderate	–	–	1 (7)	–	1 (2)
Severe	–	–	1 (7)	1 (7)	2 (3)
Dose 2					
None	13 (100)	15 (100)	13 (87)	11 (79)	52 (91)
Any severity	–	–	2 (13)	3 (21)	5 (9)
Mild	–	–	1 (7)	–	1 (2)
Moderate	–	–	–	2 (14)	2 (4)
Severe	–	–	1 (7)	1 (7)	2 (4)

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Any dose					
None	15 (100)	15 (100)	13 (87)	12 (80)	55 (92)
Any severity	–	–	2 (13)	3 (20)	5 (8)
Mild	–	–	–	–	–
Moderate	–	–	1 (7)	2 (13)	3 (5)
Severe	–	–	1 (7)	1 (7)	2 (3)
Induration/Swelling					
Dose 1					
None	15 (100)	12 (80)	12 (80)	11 (73)	50 (83)
Any severity	–	3 (20)	3 (20)	4 (27)	10 (17)
Mild	–	3 (20)	3 (20)	3 (20)	9 (15)
Moderate	–	–	–	1 (7)	1 (2)
Severe	–	–	–	–	–
Dose 2					
None	13 (100)	15 (100)	14 (93)	11 (79)	53 (93)
Any severity	–	–	1 (7)	3 (21)	4 (7)
Mild	–	–	1 (7)	2 (14)	3 (5)
Moderate	–	–	–	1 (7)	1 (2)
Severe	–	–	–	–	–
Any dose					
None	15 (100)	12 (80)	12 (80)	11 (73)	50 (83)
Any severity	–	3 (20)	3 (20)	4 (27)	10 (17)
Mild	–	3 (20)	3 (20)	3 (20)	9 (15)
Moderate	–	–	–	1 (7)	1 (2)
Severe	–	–	–	–	–
Induration/Swelling Measurement (mm)					
Dose 1					
None	15 (100)	14 (93)	13 (87)	12 (80)	54 (90)
Any severity	–	1 (7)	2 (13)	3 (20)	6 (10)
Mild	–	–	2 (13)	1 (7)	3 (5)
Moderate	–	1 (7)	–	1 (7)	2 (3)
Severe	–	–	–	1 (7)	1 (2)

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Dose Severity, n (%)	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Dose 2					
None	13 (100)	15 (100)	14 (93)	11 (79)	53 (93)
Any severity	–	–	1 (7)	3 (21)	4 (7)
Mild	–	–	–	1 (7)	1 (2)
Moderate	–	–	1 (7)	2 (14)	3 (5)
Severe	–	–	–	–	–
Any dose					
None	15 (100)	14 (93)	13 (87)	11 (73)	53 (88)
Any severity	–	1 (7)	2 (13)	4 (27)	7 (12)
Mild	–	–	1 (7)	2 (13)	3 (5)
Moderate	–	1 (7)	1 (7)	1 (7)	3 (5)
Severe	–	–	–	1 (7)	1 (2)
Pain					
Dose 1					
None	5 (33)	2 (13)	1 (7)	-	8 (13)
Any severity	10 (67)	13 (87)	14 (93)	15 (100)	52 (87)
Mild	10 (67)	11 (73)	12 (80)	9 (60)	42 (70)
Moderate	–	2 (13)	2 (13)	6 (40)	10 (17)
Severe	–	–	–	–	–
Dose 2					
None	3 (23)	2 (13)	-	-	5 (9)
Any severity	10 (77)	13 (87)	15 (100)	14 (100)	52 (91)
Mild	9 (69)	10 (67)	11 (73)	10 (71)	40 (70)
Moderate	1 (8)	3 (20)	4 (27)	4 (29)	12 (21)
Severe	–	–	–	–	–
Any dose					
None	4 (27)	1 (7)	-	-	5 (8)
Any severity	11 (73)	14 (93)	15 (100)	15 (100)	55 (92)
Mild	10 (67)	10 (67)	10 (67)	8 (53)	38 (63)
Moderate	1 (7)	4 (27)	5 (33)	7 (47)	17 (28)
Severe	–	–	–	–	–

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

The following symptoms reported by the participant were mapped to the database as follows: redness = erythema/redness; swelling/hardness = induration/swelling.

Source: Posttext Table 77.

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Table 17: Number and Percentage of Participants Reporting Solicited Local Adverse Reactions (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
Dose Severity, n (%)	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Any Local Symptom				
Dose 1				
None	5 (50)	4 (40)	2 (20)	11 (37)
Any severity	5 (50)	6 (60)	8 (80)	19 (63)
Mild	5 (50)	4 (40)	8 (80)	17 (57)
Moderate	–	2 (20)	–	2 (7)
Severe	–	–	–	–
Dose 2				
None	4 (40)	2 (20)	1 (11)	7 (24)
Any severity	6 (60)	8 (80)	8 (89)	22 (76)
Mild	4 (40)	7 (70)	6 (67)	17 (59)
Moderate	2 (20)	–	2 (22)	4 (14)
Severe	–	1 (10)	–	1 (3)
Any dose				
None	2 (20)	1 (10)	1 (10)	4 (13)
Any severity	8 (80)	9 (90)	9 (90)	26 (87)
Mild	6 (60)	6 (60)	7 (70)	19 (63)
Moderate	2 (20)	2 (20)	2 (20)	6 (20)
Severe	-	1 (10)	-	1 (3)
Erythema/Redness				
Dose 1				
None	9 (90)	10 (100)	9 (90)	28 (93)
Any severity	1 (10)	–	1 (10)	2 (7)
Mild	1 (10)	–	1 (10)	2 (7)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	9 (90)	9 (90)	7 (78)	25 (86)
Any severity	1 (10)	1 (10)	2 (22)	4 (14)
Mild	1 (10)	–	2 (22)	3 (10)
Moderate	–	–	–	–
Severe	–	1 (10)	–	1 (3)

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	9 (90)	9 (90)	7 (70)	25 (83)
Any severity	1 (10)	1 (10)	3 (30)	5 (17)
Mild	1 (10)	–	3 (30)	4 (13)
Moderate	–	–	–	–
Severe	–	1 (10)	–	1 (3)
Erythema/Redness Measurement (mm)				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	9 (90)	9 (90)	8 (89)	26 (90)
Any severity	1 (10)	1 (10)	1 (11)	3 (10)
Mild	–	–	1 (11)	1 (3)
Moderate	1 (10)	–	–	1 (3)
Severe	–	1 (10)	–	1 (3)
Any dose				
None	9 (90)	9 (90)	9 (90)	27 (90)
Any severity	1 (10)	1 (10)	1 (11)	3 (10)
Mild	–	–	1 (10)	1 (3)
Moderate	1 (10)	–	–	1 (3)
Severe	–	1 (10)	–	1 (3)
Induration/Swelling				
Dose 1				
None	8 (80)	8 (80)	7 (70)	23 (77)
Any severity	2 (20)	2 (20)	3 (30)	7 (23)
Mild	2 (20)	–	3 (30)	5 (17)
Moderate	–	2 (20)	–	2 (7)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Dose 2				
None	6 (60)	9 (90)	7 (78)	22 (76)
Any severity	4 (40)	1 (10)	2 (22)	7 (24)
Mild	4 (40)	–	1 (11)	5 (17)
Moderate	–	1 (10)	1 (11)	2 (7)
Severe	–	–	–	–
Any dose				
None	5 (50)	7 (70)	7 (70)	19 (63)
Any severity	5 (50)	3 (30)	3 (30)	11 (37)
Mild	5 (50)	–	2 (20)	7 (23)
Moderate	–	3 (30)	1 (10)	4 (13)
Severe	–	–	–	–
Induration/Swelling Measurement (mm)				
Dose 1				
None	9 (90)	8 (80)	10 (100)	27 (90)
Any severity	1 (10)	2 (20)	–	3 (10)
Mild	1 (10)	–	–	1 (3)
Moderate	–	2 (20)	–	2 (7)
Severe	–	–	–	–
Dose 2				
None	8 (80)	9 (90)	8 (89)	25 (86)
Any severity	2 (20)	1 (10)	1 (11)	4 (14)
Mild	–	–	–	–
Moderate	2 (20)	1 (10)	1 (11)	4 (14)
Severe	–	–	–	–
Any dose				
None	7 (70)	7 (70)	9 (90)	23 (77)
Any severity	3 (30)	3 (30)	1 (10)	7 (23)
Mild	1 (10)	–	–	1 (3)
Moderate	2 (20)	3 (30)	1 (10)	6 (20)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Pain				
Dose 1				
None	7 (70)	4 (40)	2 (20)	13 (43)
Any severity	3 (30)	6 (60)	8 (80)	17 (57)
Mild	3 (30)	6 (60)	8 (80)	17 (57)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	5 (50)	2 (20)	1 (11)	8 (28)
Any severity	5 (50)	8 (80)	8 (89)	21 (72)
Mild	5 (50)	7 (70)	6 (67)	18 (62)
Moderate	–	1 (10)	2 (22)	3 (10)
Severe	–	–	–	–
Any dose				
None	4 (40)	1 (10)	1 (10)	6 (20)
Any severity	6 (60)	9 (90)	9 (90)	24 (80)
Mild	6 (60)	8 (80)	7 (70)	21 (70)
Moderate	–	1 (10)	2 (20)	3 (10)
Severe	–	–	–	–

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.

Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.

The following symptoms reported by the participant were mapped to the database as follows: redness = erythema/redness; swelling/hardness = induration/swelling.

Source: Posttext Table 80.

FDA-CBER-2022-1614-0667901

Table 18: Number and Percentage of Participants Reporting Solicited Local Adverse Reactions (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
Dose Severity, n (%)	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Any Local Symptom				
Dose 1				
None	4 (40)	3 (30)	2 (20)	9 (30)
Any severity	6 (60)	7 (70)	8 (80)	21 (70)
Mild	6 (60)	7 (70)	8 (80)	21 (70)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	3 (30)	6 (60)	-	9 (30)
Any severity	7 (70)	4 (40)	10 (100)	21 (70)
Mild	5 (50)	4 (40)	6 (60)	15 (50)
Moderate	2 (20)	–	4 (40)	6 (20)
Severe	–	–	–	–
Any dose				
None	2 (20)	3 (30)	-	5 (17)
Any severity	8 (80)	7 (70)	10 (100)	25 (83)
Mild	6 (60)	7 (70)	6 (60)	19 (63)
Moderate	2 (20)	–	4 (40)	6 (20)
Severe	–	–	–	–
Erythema/Redness				
Dose 1				
None	9 (90)	9 (90)	10 (100)	28 (93)
Any severity	1 (10)	1 (10)	–	2 (7)
Mild	1 (10)	1 (10)	–	2 (7)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	7 (70)	10 (100)	6 (60)	23 (77)
Any severity	3 (30)	–	4 (40)	7 (23)
Mild	3 (30)	–	4 (40)	7 (23)
Moderate	–	–	–	–
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Any dose				
None	7 (70)	9 (90)	6 (60)	22 (73)
Any severity	3 (30)	1 (10)	4 (40)	8 (27)
Mild	3 (30)	1 (10)	4 (40)	8 (27)
Moderate	–	–	–	–
Severe	–	–	–	–
Erythema/Redness Measurement (mm)				
Dose 1				
None	10 (100)	10 (100)	10 (100)	30 (100)
Any severity	–	–	–	–
Mild	–	–	–	–
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	8 (80)	10 (100)	8 (80)	26 (87)
Any severity	2 (20)	–	2 (20)	4 (13)
Mild	–	–	1 (10)	1 (3)
Moderate	2 (20)	–	1 (10)	3 (10)
Severe	–	–	–	–
Any dose				
None	8 (80)	10 (100)	8 (80)	26 (87)
Any severity	2 (20)	–	2 (20)	4 (13)
Mild	–	–	1 (10)	1 (3)
Moderate	2 (20)	–	1 (10)	3 (10)
Severe	–	–	–	–
Induration/Swelling				
Dose 1				
None	10 (100)	8 (80)	10 (100)	28 (93)
Any severity	–	2 (20)	–	2 (7)
Mild	–	2 (10)	–	2 (7)
Moderate	–	–	–	–
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Dose 2				
None	8 (80)	10 (100)	7 (70)	25 (83)
Any severity	2 (20)	–	3 (30)	5 (17)
Mild	2 (20)	–	3 (30)	5 (17)
Moderate	–	–	–	–
Severe	–	–	–	–
Any dose				
None	8 (80)	8 (80)	7 (70)	23 (77)
Any severity	2 (20)	2 (20)	3 (30)	7 (23)
Mild	2 (20)	2 (20)	3 (30)	7 (23)
Moderate	–	–	–	–
Severe	–	–	–	–
Induration/Swelling Measurement (mm)				
Dose 1				
None	10 (100)	9 (90)	10 (100)	29 (97)
Any severity	–	1 (10)	–	1 (3)
Mild	–	1 (10)	–	1 (3)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	8 (80)	10 (100)	7 (70)	25 (83)
Any severity	2 (20)	–	3 (30)	5 (17)
Mild	–	–	–	–
Moderate	2 (20)	–	3 (30)	5 (17)
Severe	–	–	–	–
Any dose				
None	8 (80)	9 (90)	7 (70)	24 (80)
Any severity	2 (20)	1 (10)	3 (30)	6 (20)
Mild	–	1 (10)	–	1 (3)
Moderate	2 (20)	–	3 (30)	5 (17)
Severe	–	–	–	–

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Dose Severity, n (%)	mRNA-1273 Dose Level 25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Pain				
Dose 1				
None	4 (40)	3 (30)	2 (20)	9 (30)
Any severity	6 (60)	7 (70)	8 (80)	21 (70)
Mild	6 (60)	7 (70)	8 (80)	21 (70)
Moderate	–	–	–	–
Severe	–	–	–	–
Dose 2				
None	4 (40)	6 (60)	-	10 (33)
Any severity	6 (60)	4 (40)	10 (100)	20 (67)
Mild	6 (60)	4 (40)	9 (90)	19 (63)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–
Any dose				
None	2 (20)	3 (30)	-	5 (17)
Any severity	8 (80)	7 (70)	10 (100)	25 (83)
Mild	8 (80)	7 (70)	9 (90)	24 (80)
Moderate	–	–	1 (10)	1 (3)
Severe	–	–	–	–

Note: Severity is the maximum severity reported over all solicited symptoms after dosing for each participant.
Total number of participants for solicited adverse reaction after Dose 2 included the participants who received the second vaccination.
The following symptoms reported by the participant were mapped to the database as follows: redness = erythema/redness; swelling/hardness = induration/swelling.
Source: Posttext Table 83.

7.1.4 Onset of Solicited Adverse Reactions

Age Group: 18 to 55 Years

Most of the participants reported solicited systemic ARs within 2 days after the first (Figure 4) and second (Figure 5) injections, and all solicited local ARs were reported within 2 days after the first (Figure 10) and second (Figure 11) injections.

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Age Group: 56 to 70 Years

Most of the participants reported solicited systemic ARs within 2 days after the first (Figure 6) and second (Figure 7) injections, and all solicited local ARs were reported within 2 days after the first (Figure 12) and second (Figure 13) injections.

Age Group: ≥ 71 Years

Most of the participants reported solicited systemic ARs within 2 days after the first (Figure 8) and second (Figure 9) injections, and all solicited local ARs were reported within 2 days after the first (Figure 14) and second (Figure 15) injections except one local AR, which was reported on Day 4 after the first injection.

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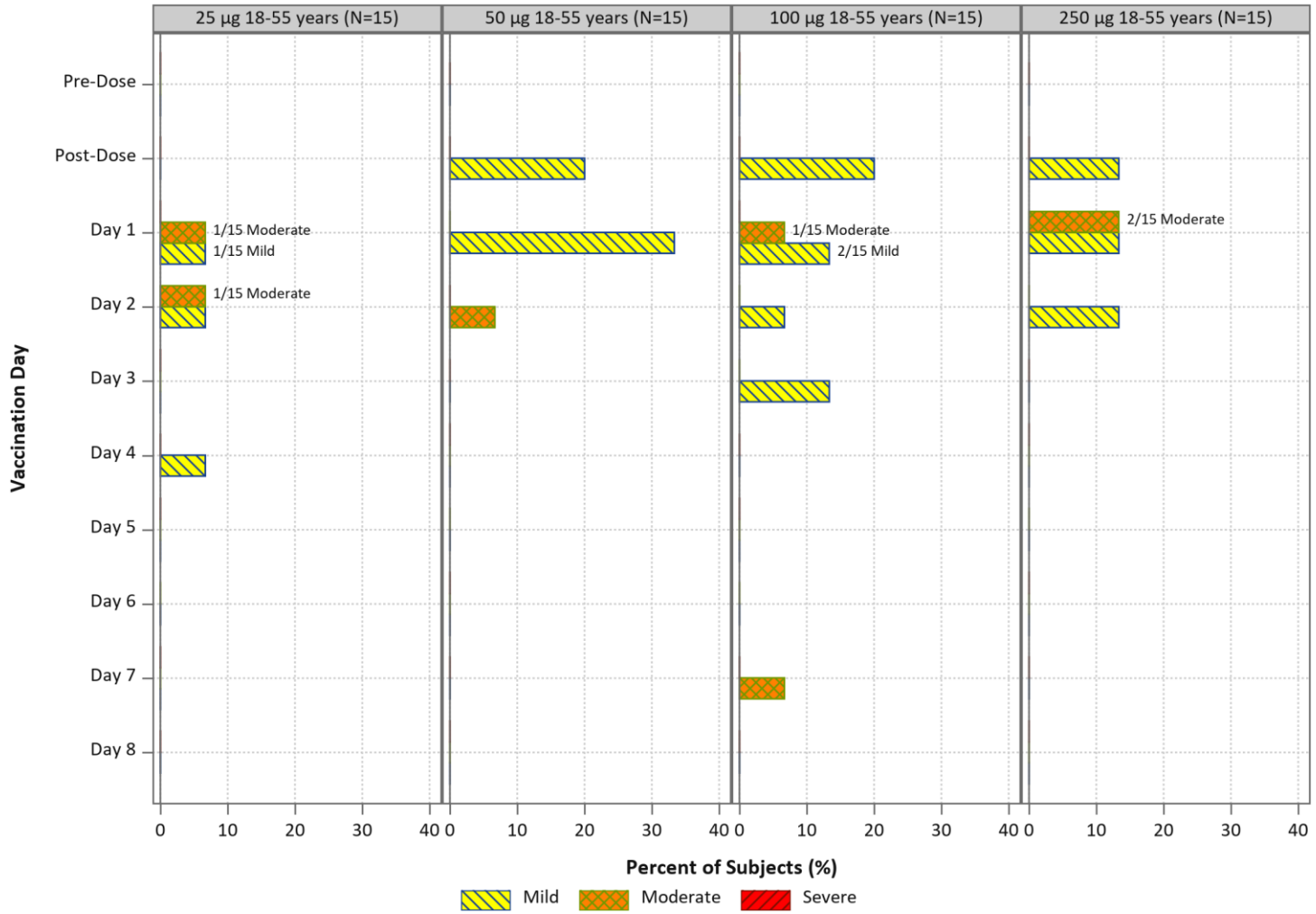
Figure 4: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (18 to 55 Years of Age)



Source: Posttext Figure 72.

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Figure 5: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (18 to 55 Years of Age)



Source: Posttext Figure 78.

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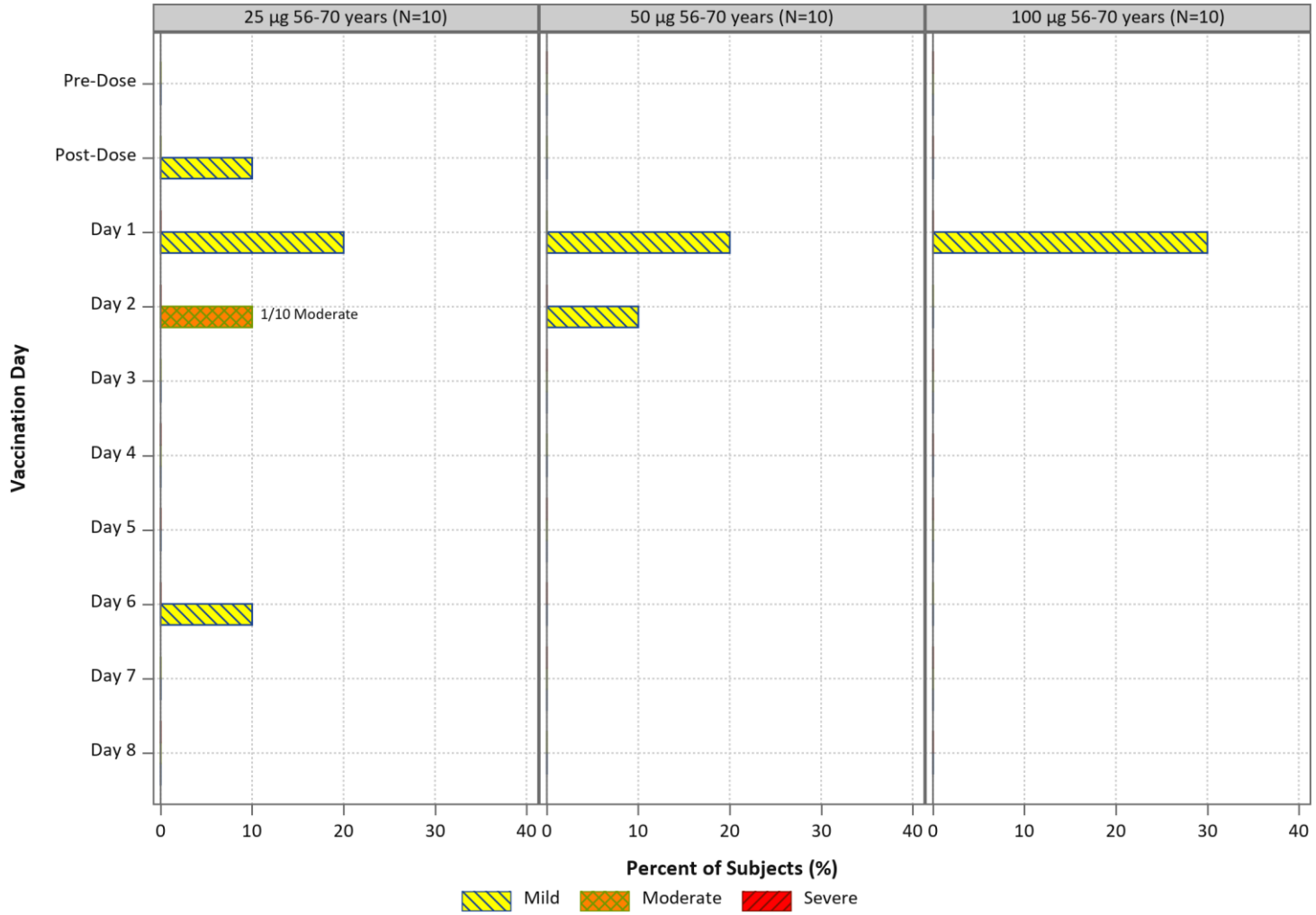
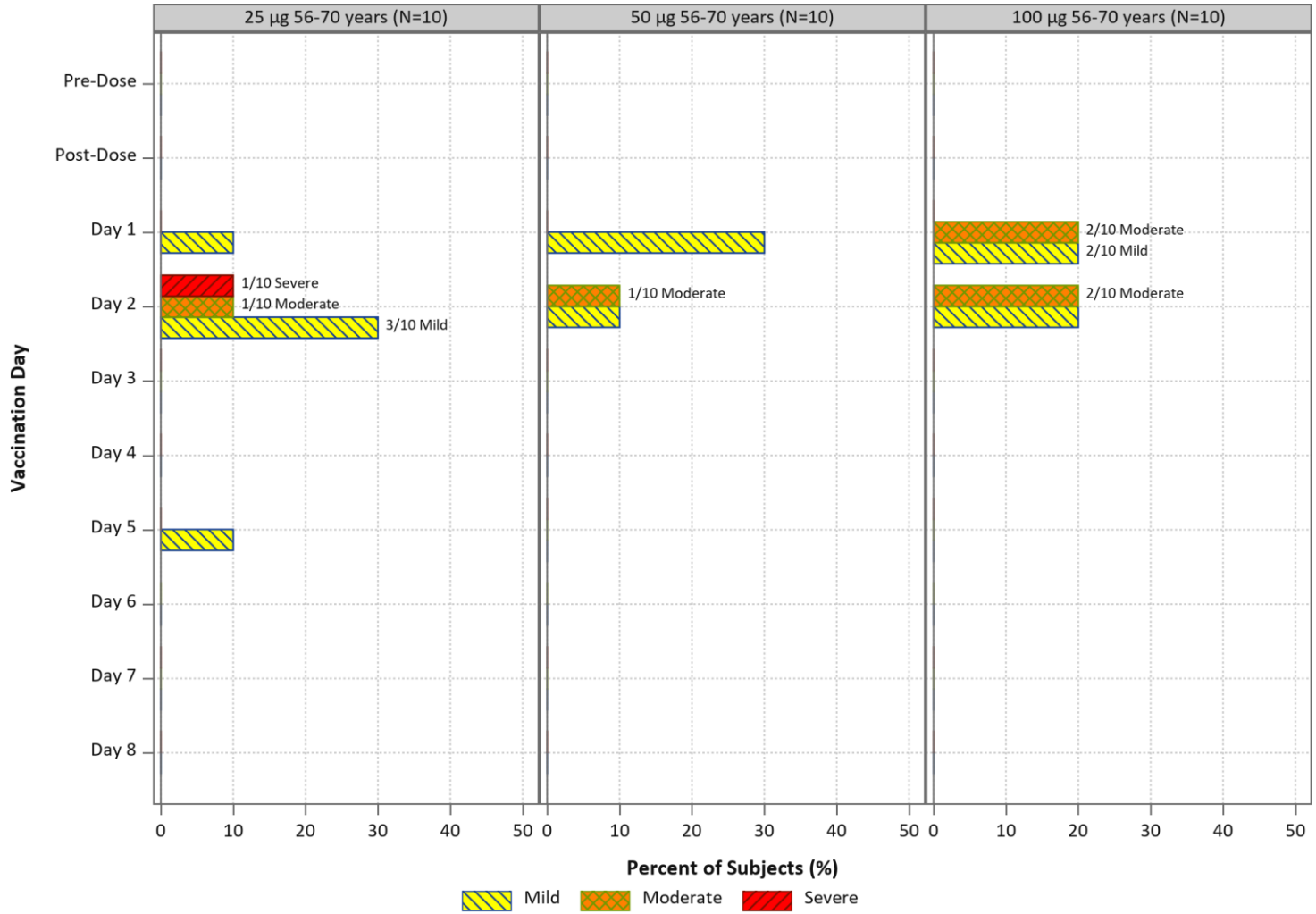
Figure 6: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (56 to 70 Years of Age)



Source: Posttext Figure 73.

FDA-CBER-2022-1614-0667909

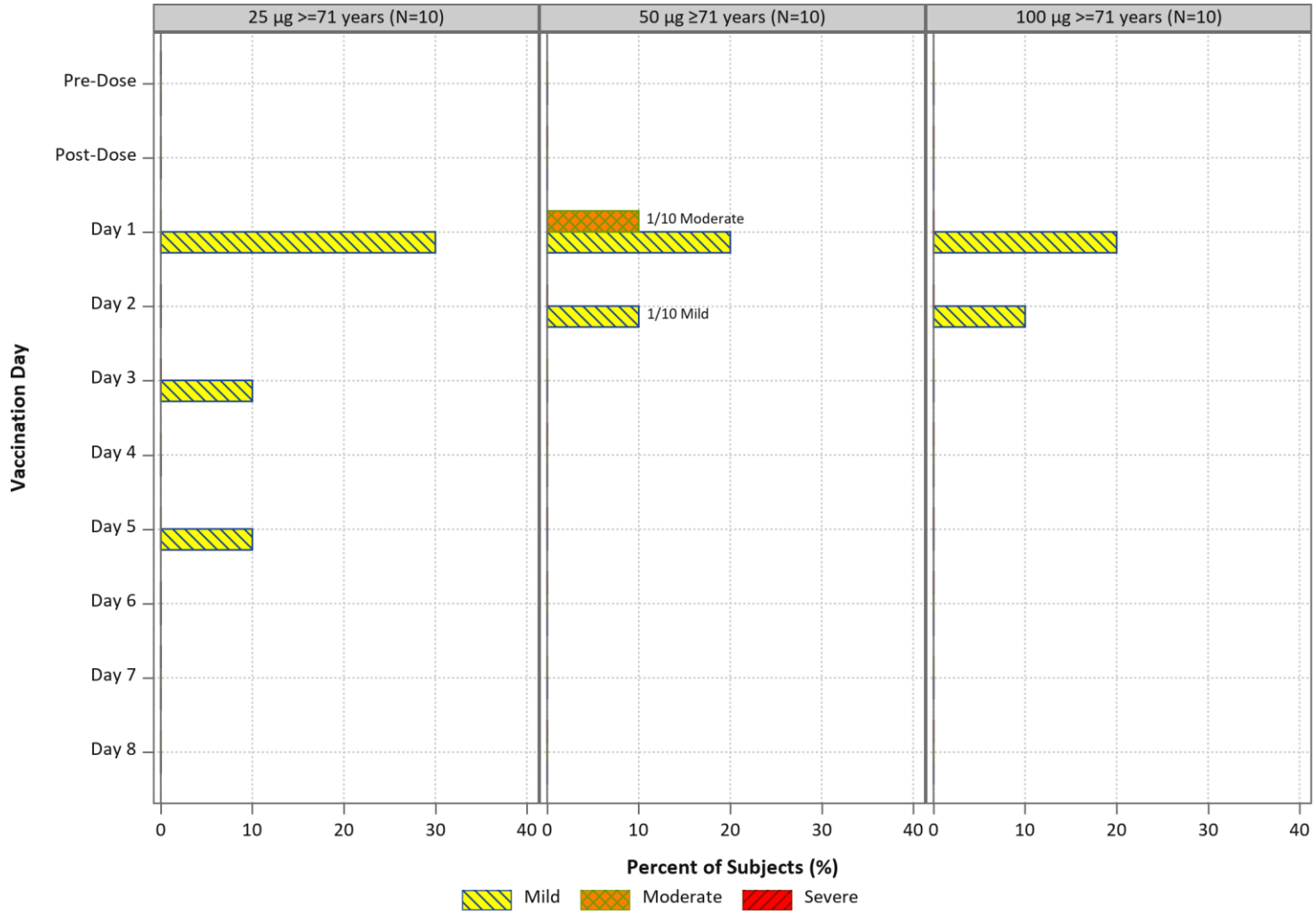
Figure 7: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (56 to 70 Years of Age)



Source: Posttext Figure 79.

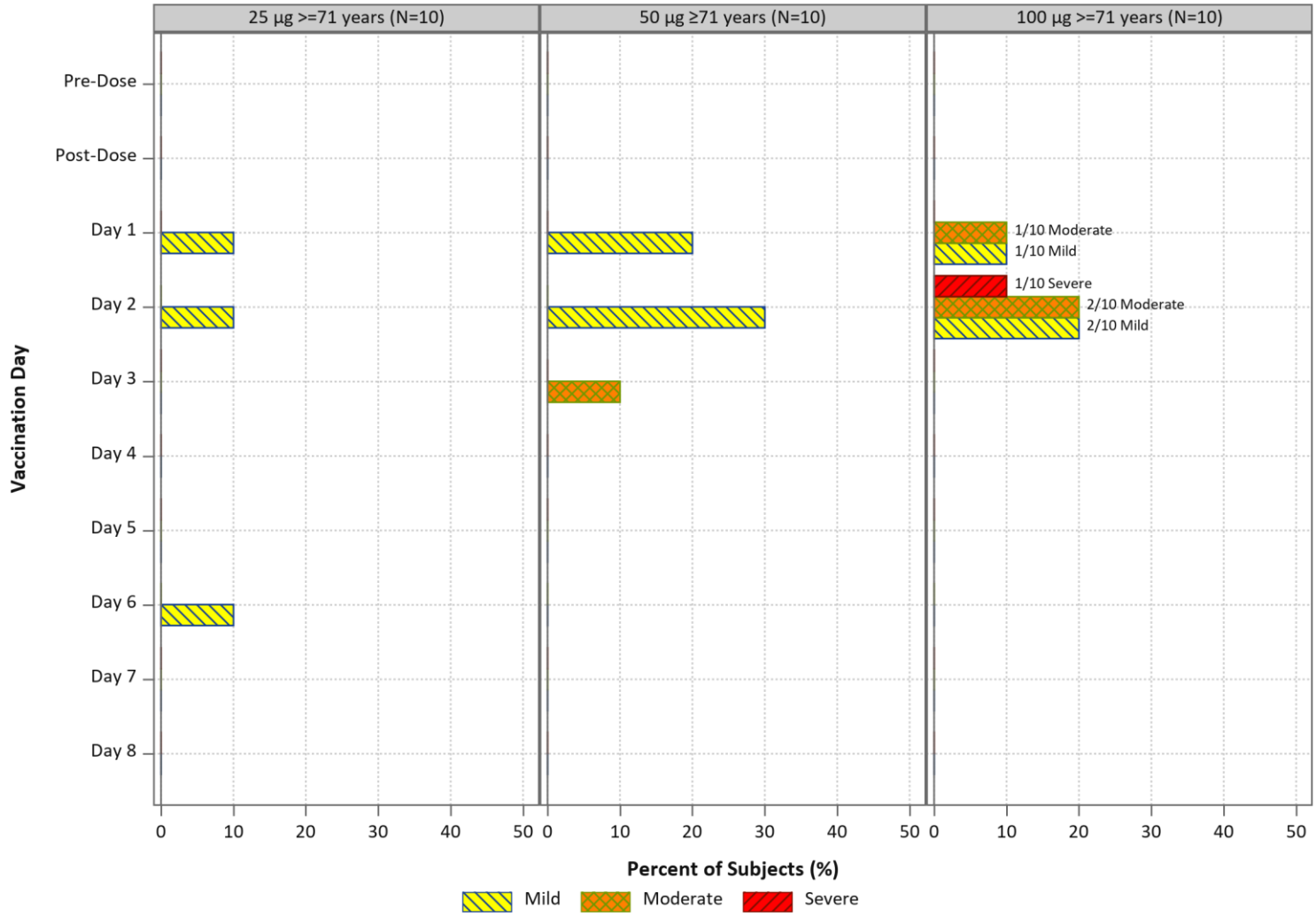
FDA-CBER-2022-1614-0667910

Figure 8: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (≥ 71 Years of Age)



Source: Posttext Figure 74.

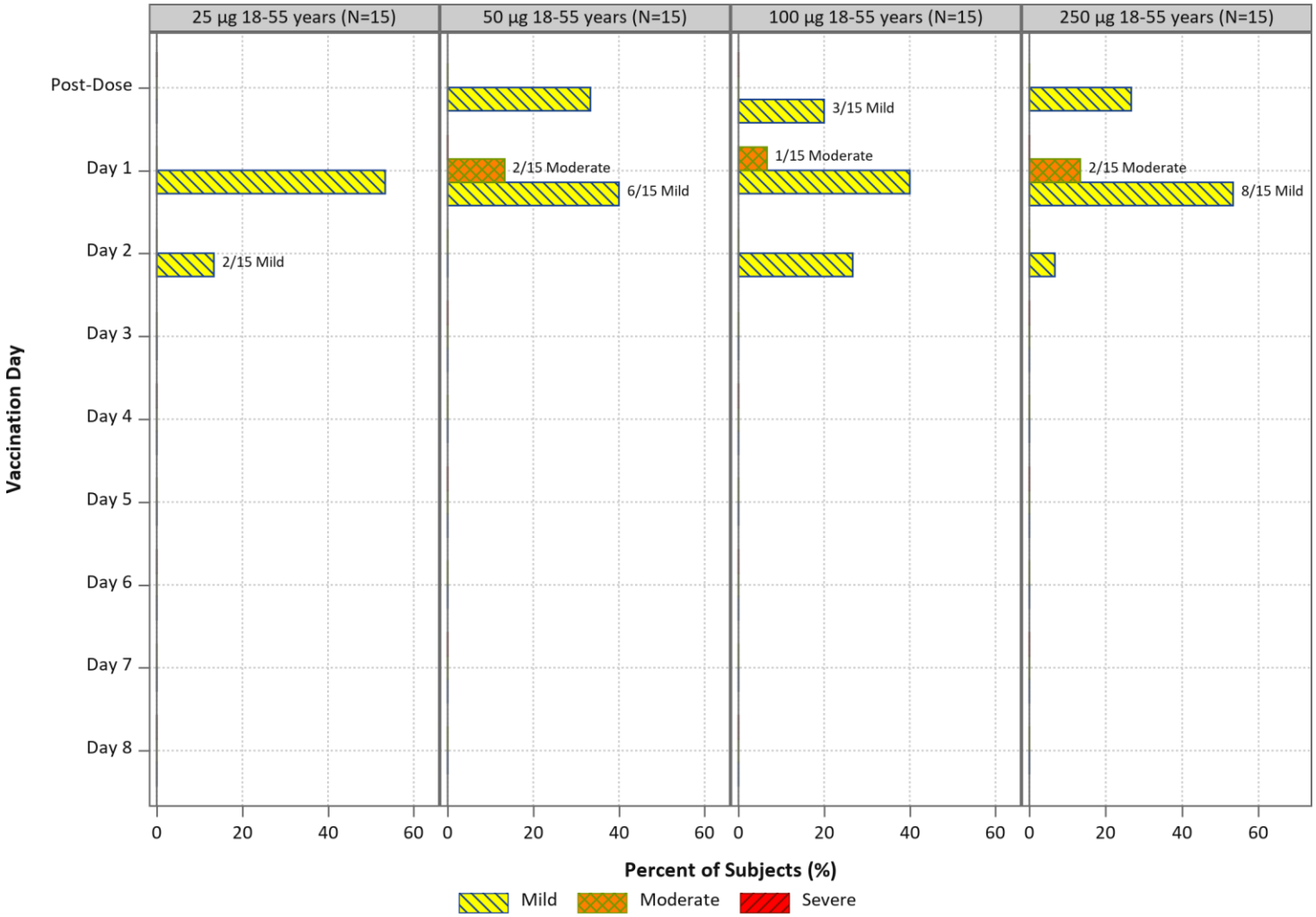
Figure 9: Day of Onset and Maximum Severity of Solicited Systemic Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (≥ 71 Years of Age)



Source: Posttext Figure 80.

FDA-CBER-2022-1614-0667912

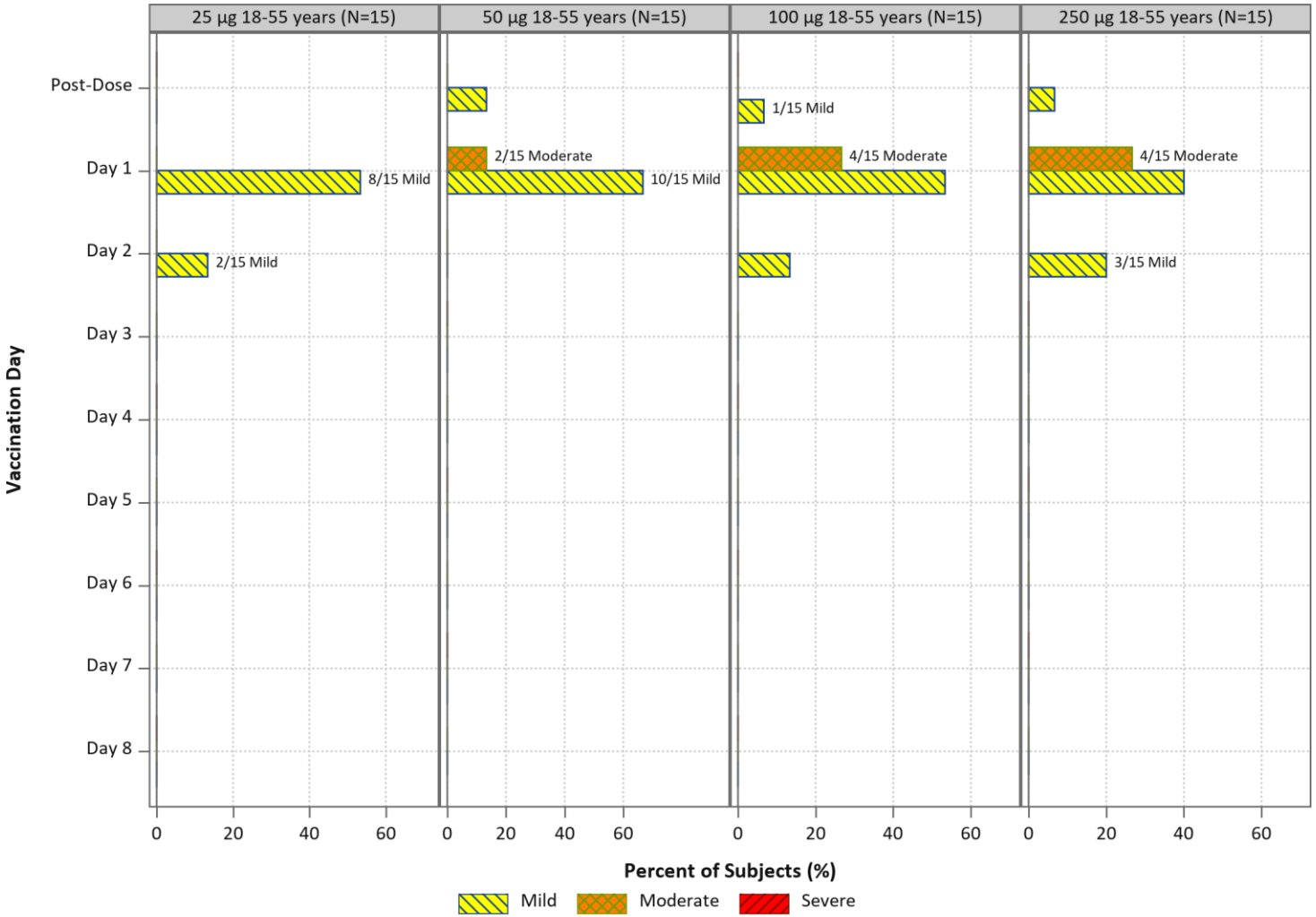
Figure 10: Day of Onset and Maximum Severity of Solicited Local Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (18 to 55 Years of Age)



Source: Posttext Figure 75.

FDA-CBER-2022-1614-0667913

Figure 11: Day of Onset and Maximum Severity of Solicited Local Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (18 to 55 Years of Age)



Source: Posttext Figure 81.

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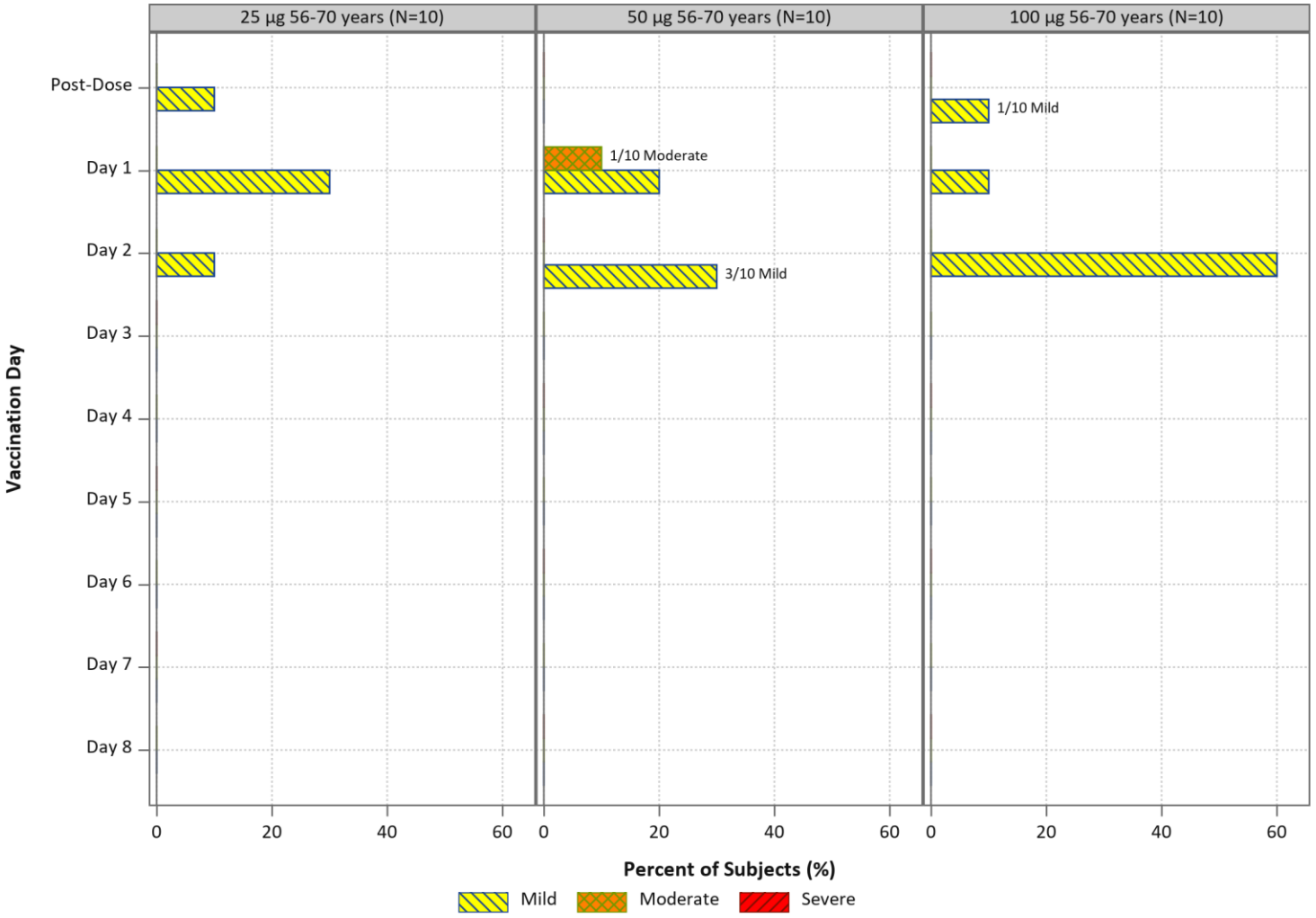
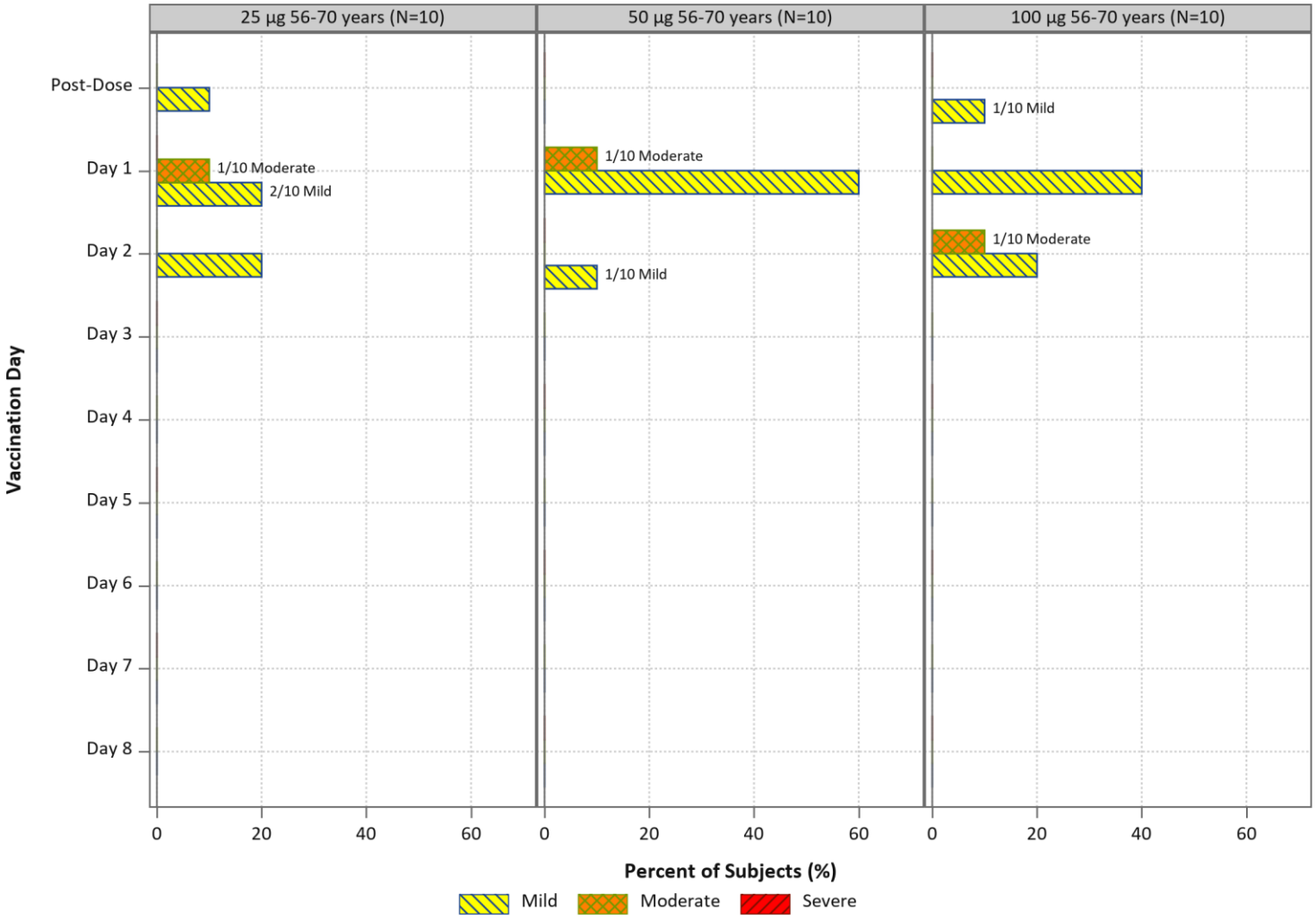
Figure 12: Day of Onset and Maximum Severity of Solicited Local Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (56 to 70 Years of Age)



Source: Posttext Figure 76.

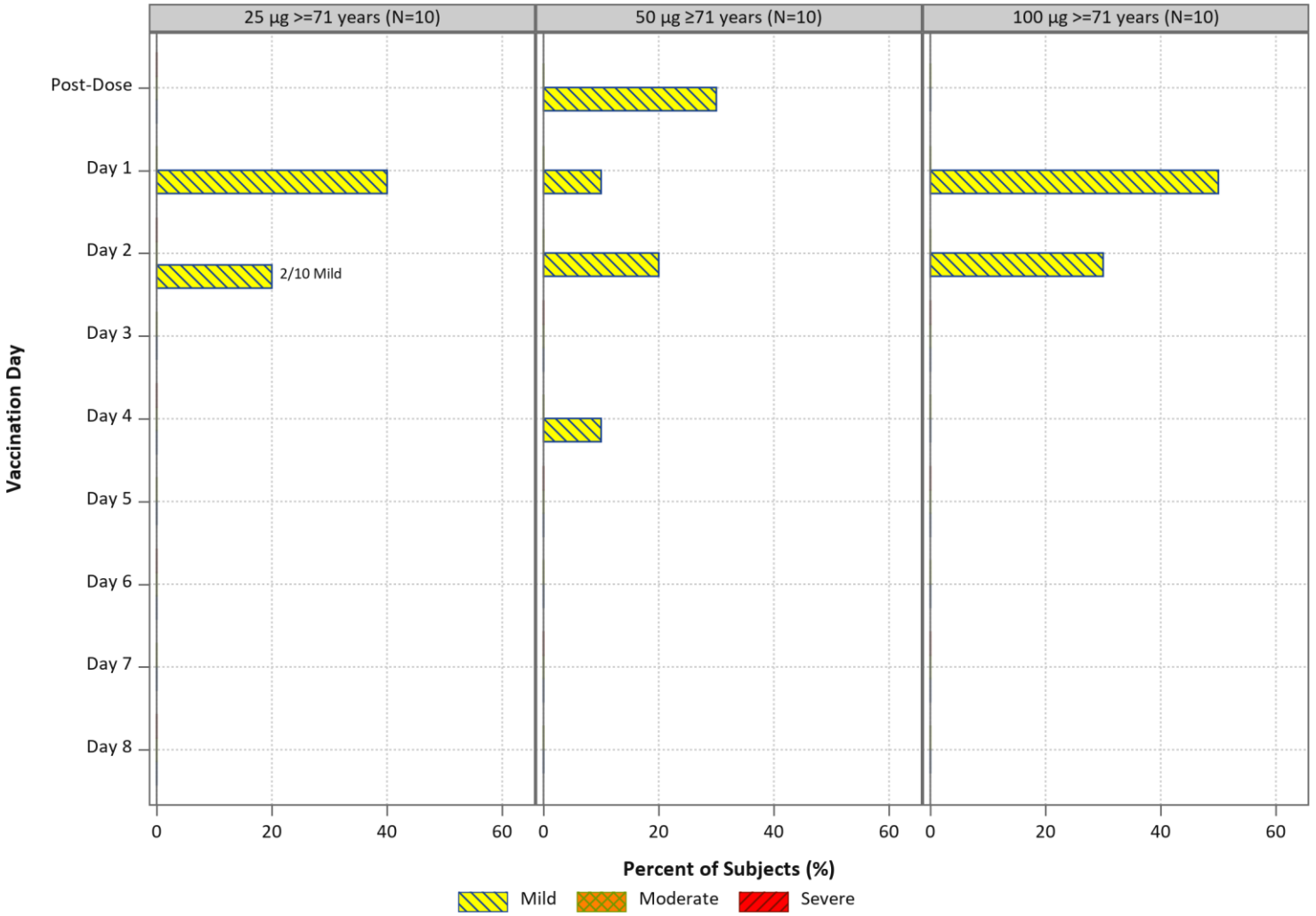
Figure 13: Day of Onset and Maximum Severity of Solicited Local Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (56 to 70 Years of Age)



Source: Posttext Figure 82.

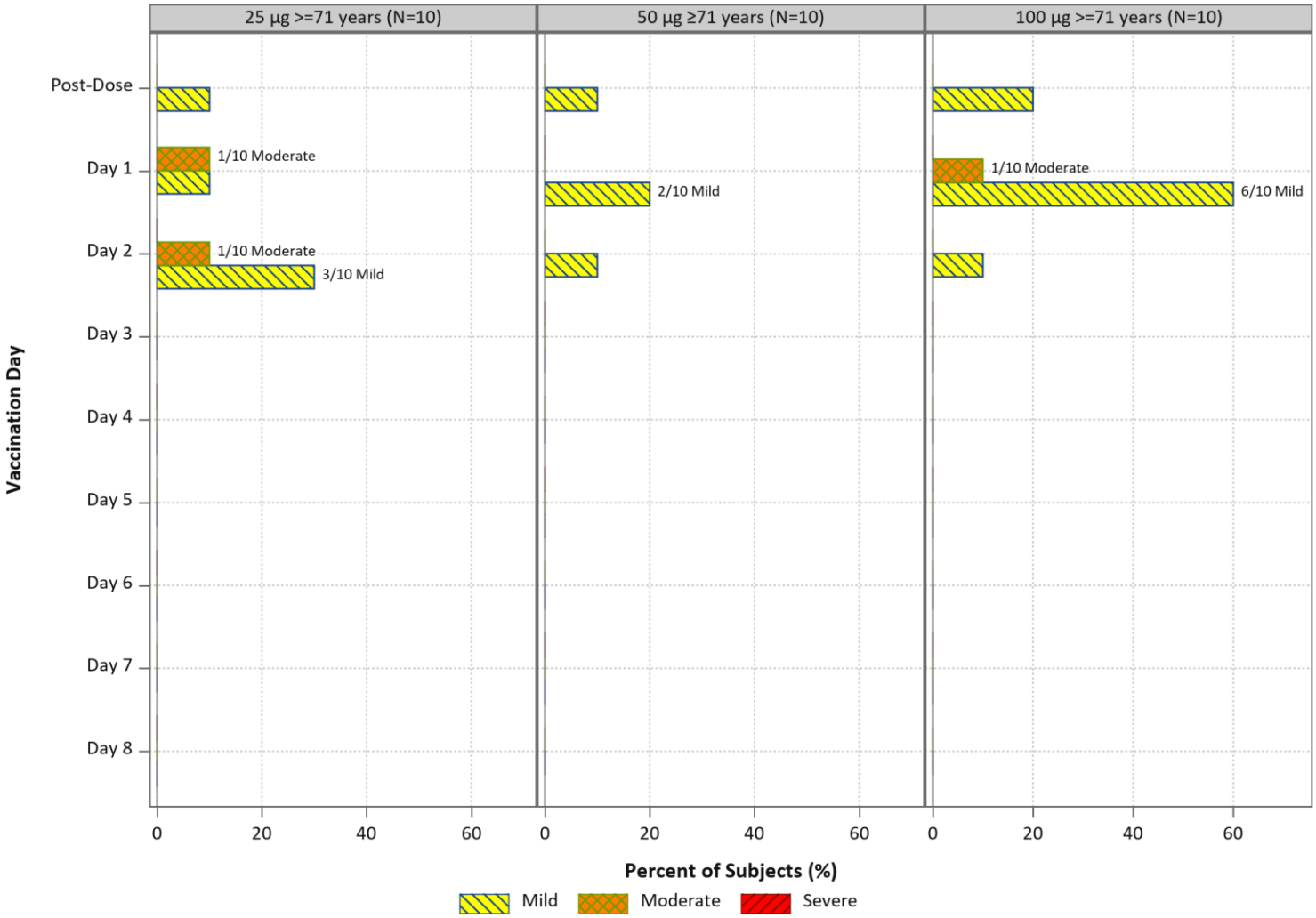
FDA-CBER-2022-1614-0667916

Figure 14: Day of Onset and Maximum Severity of Solicited Local Symptoms After the First Injection by Days Post Vaccination and Vaccination Group (≥ 71 Years of Age)



Source: Posttext Figure 77.

Figure 15: Day of Onset and Maximum Severity of Solicited Local Symptoms After the Second Injection by Days Post Vaccination and Vaccination Group (≥ 71 Years of Age)



Source: Posttext Figure 83.

7.1.5 Number of Days Reporting Solicited Adverse Reactions

Age Group: 18 to 55 Years

The median duration of solicited ARs was 1 day (range: 1 to 6). The median duration of solicited systemic ARs was 1 day (range: 1 to 6), and the median duration of solicited local ARs was 2 days (range: 1 to 5) (Table 19). Notably, all severe solicited ARs resolved within 1 to 2 days (Listing 10 and Listing 11).

The median duration of solicited ARs after the first injection (2 days [range: 1 to 6]) was similar to that after the second injection (1 day [range: 1 to 6]). The median durations of solicited systemic ARs and solicited local ARs after the first injection (1 day [range: 1 to 6] and 2 days [range: 1 to 5], respectively; Table 22) were the same as those after the second injection (1 day [range: 1 to 6] and 2 days [range: 1 to 5], respectively; Table 25).

No clinically relevant dose-dependent trends were observed in the duration of solicited ARs among the vaccination groups.

Age Group: 56 to 70 Years

The median duration of solicited ARs was 1 day (range: 1 to 8). The median duration of solicited systemic ARs was 1 day (range: 1 to 5), and the median duration of solicited local ARs was 2 days (range: 1 to 8) (Table 20). One participant in the 25 µg vaccination group reported a solicited local AR of mild erythema 1 day after the first injection that lasted for 8 days; all other solicited ARs lasted for 1 to 6 days. Notably, all severe solicited ARs resolved within 1 day (Listing 10 and Listing 11).

The median duration of solicited ARs after the first injection (1 day [range: 1 to 8]) was similar to that after the second injection (1 day [range: 1 to 5]). The median durations of solicited systemic ARs and solicited local ARs after the first injection (1 day [range: 1 to 2] and 2 days [range: 1 to 8], respectively; Table 23) were similar to those after the second injection (1 day [range: 1 to 5] and 2 days [range: 1 to 5], respectively; Table 26).

No clinically relevant dose-dependent trends were observed in the number of days reporting solicited ARs among the vaccination groups.

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Age Group: ≥ 71 Years

The median duration of solicited ARs was 1 day (range: 1 to 6). The median duration of solicited systemic ARs was 1 day (range: 1 to 6), and the median duration of solicited local ARs was 2 days (range: 1 to 6) (Table 21). Notably, the severe solicited AR resolved within 1 day (Listing 10).

The median duration of solicited ARs after the first injection (1 day [range: 1 to 6]) was the same as after the second injection (1 day [range: 1 to 6]). The median durations of solicited systemic ARs and solicited local ARs after the first injection (1 day [range: 1 to 6] and 2 days [range: 1 to 5], respectively; Table 24) were similar to those after the second injection (1 day [range: 1 to 5] and 2 days [range: 1 to 6] respectively; Table 27).

No clinically relevant dose-dependent trends were observed in the number of days reporting solicited ARs among the vaccination groups.

Table 19: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After Any Injection (18 to 55 Years of Age)

	mRNA-1273 Dose Level				
Category Statistic	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	All Participants (N=60)
Any symptom					
n	48	87	111	144	390
Mean (SD)	1.4 (0.7)	1.7 (0.9)	1.7 (0.9)	2.0 (1.1)	1.8 (1.0)
Median	1.0	1.0	1.0	2.0	1.0
Min, Max	1, 3	1, 6	1, 5	1, 6	1, 6
Any systemic symptom					
n	26	53	70	97	246
Mean (SD)	1.1 (0.3)	1.6 (1.0)	1.4 (0.6)	1.8 (1.0)	1.6 (0.9)
Median	1.0	1.0	1.0	2.0	1.0
Min, Max	1, 2	1, 6	1, 4	1, 6	1, 6
Any local symptom					
n	22	34	41	47	144
Mean (SD)	1.9 (0.8)	1.9 (0.9)	2.1 (1.1)	2.4 (1.1)	2.2 (1.0)
Median	2.0	2.0	2.0	3.0	2.0
Min, Max	1, 3	1, 4	1, 5	1, 5	1, 5

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 84.

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Table 20: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After Any Injection (56 to 70 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	51	37	65	153
Mean (SD)	1.6 (1.2)	1.9 (1.1)	1.7 (0.9)	1.7 (1.0)
Median	1.0	2.0	1.0	1.0
Min, Max	1, 8	1, 5	1, 5	1, 8
Any systemic symptom				
n	32	19	40	91
Mean (SD)	1.4 (0.8)	1.5 (1.0)	1.5 (0.8)	1.5 (0.8)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 4	1, 5	1, 4	1, 5
Any local symptom				
n	19	18	25	62
Mean (SD)	1.9 (1.6)	2.3 (1.1)	1.9 (1.1)	2.0 (1.3)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 8	1, 5	1, 5	1, 8

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 85.

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Table 21: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After Any Injection (≥ 71 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	34	31	61	126
Mean (SD)	1.7 (1.3)	2.0 (1.3)	1.7 (1.0)	1.8 (1.2)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 6	1, 5	1, 4	1, 6
Any systemic symptom				
n	15	14	35	64
Mean (SD)	1.5 (1.4)	1.7 (1.2)	1.3 (0.6)	1.4 (1.0)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 6	1, 5	1, 3	1, 6
Any local symptom				
n	19	17	26	62
Mean (SD)	1.9 (1.3)	2.2 (1.4)	2.2 (1.1)	2.1 (1.2)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 6	1, 5	1, 4	1, 6

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 86.

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Table 22: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the First Injection (18 to 55 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=15)	 50 µg (N=15)	 100 µg (N=15)	 250 µg (N=15)	All Participants (N=60)
Any symptom					
n	21	35	34	47	137
Mean (SD)	1.3 (0.6)	1.9 (1.1)	1.5 (0.6)	2.2 (1.2)	1.8 (1.0)
Median	1.0	2.0	1.5	2.0	2.0
Min, Max	1, 3	1, 6	1, 3	1, 5	1, 6
Any systemic symptom					
n	11	18	12	22	63
Mean (SD)	1.0 (0.0)	1.7 (1.3)	1.3 (0.5)	2.2 (1.3)	1.7 (1.1)
Median	1.0	1.0	1.0	2.0	1.0
Min, Max	1, 1	1, 6	1, 2	1, 5	1, 6
Any local symptom					
n	10	17	22	25	74
Mean (SD)	1.7 (0.7)	2.1 (0.9)	1.7 (0.6)	2.3 (1.2)	2.0 (0.9)
Median	2.0	2.0	2.0	2.0	2.0
Min, Max	1, 3	1, 4	1, 3	1, 5	1, 5

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 84.

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Table 23: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the First Injection (56 to 70 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	19	13	18	50
Mean (SD)	1.6 (1.6)	1.6 (0.7)	1.3 (0.5)	1.5 (1.1)
Median	1.0	2.0	1.0	1.0
Min, Max	1, 8	1, 3	1, 2	1, 8
Any systemic symptom				
n	12	5	6	23
Mean (SD)	1.3 (0.5)	1.2 (0.4)	1.2 (0.4)	1.2 (0.4)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 2	1, 2	1, 2
Any local symptom				
n	7	8	12	27
Mean (SD)	2.3 (2.6)	1.9 (0.6)	1.4 (0.5)	1.8 (1.4)
Median	1.0	2.0	1.0	2.0
Min, Max	1, 8	1, 3	1, 2	1, 8

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 85.

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Table 24: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the First Injection (≥ 71 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	18	19	14	51
Mean (SD)	1.7 (1.3)	1.9 (1.4)	1.7 (0.7)	1.8 (1.2)
Median	1.0	1.0	2.0	1.0
Min, Max	1, 6	1, 5	1, 3	1, 6
Any systemic symptom				
n	11	7	6	24
Mean (SD)	1.6 (1.6)	1.4 (0.8)	1.5 (0.8)	1.5 (1.2)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 6	1, 3	1, 3	1, 6
Any local symptom				
n	7	12	8	27
Mean (SD)	1.7 (0.8)	2.2 (1.6)	1.9 (0.6)	2.0 (1.2)
Median	2.0	1.0	2.0	2.0
Min, Max	1, 3	1, 5	1, 3	1, 5

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 86.

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Table 25: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the Second Injection (18 to 55 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=15)	 50 µg (N=15)	 100 µg (N=15)	 250 µg (N=15)	All Participants (N=60)
Any symptom					
n	27	52	77	97	253
Mean (SD)	1.5 (0.8)	1.6 (0.8)	1.7 (1.0)	1.9 (1.0)	1.8 (0.9)
Median	1.0	1.0	1.0	2.0	1.0
Min, Max	1, 3	1, 3	1, 5	1, 6	1, 6
Any systemic symptom					
n	15	35	58	75	183
Mean (SD)	1.1 (0.4)	1.5 (0.8)	1.4 (0.7)	1.7 (0.9)	1.5 (0.8)
Median	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 4	1, 6	1, 6
Any local symptom					
n	12	17	19	22	70
Mean (SD)	2.0 (0.9)	1.8 (0.8)	2.7 (1.2)	2.6 (1.0)	2.3 (1.1)
Median	2.0	2.0	3.0	3.0	2.0
Min, Max	1, 3	1, 3	1, 5	1, 4	1, 5

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 84.

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Table 26: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the Second Injection (56 to 70 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	32	24	47	103
Mean (SD)	1.6 (0.8)	2.0 (1.2)	1.8 (1.0)	1.8 (1.0)
Median	1.0	2.0	2.0	1.0
Min, Max	1, 4	1, 5	1, 5	1, 5
Any systemic symptom				
n	20	14	34	68
Mean (SD)	1.5 (0.9)	1.6 (1.1)	1.6 (0.8)	1.5 (0.9)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 4	1, 5	1, 4	1, 5
Any local symptom				
n	12	10	13	35
Mean (SD)	1.8 (0.8)	2.6 (1.3)	2.4 (1.3)	2.2 (1.1)
Median	2.0	2.5	2.0	2.0
Min, Max	1, 3	1, 5	1, 5	1, 5

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 85.

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Table 27: Summary of Duration (Days) of Reporting Solicited Adverse Reactions After the Second Injection (≥ 71 Years of Age)

Category Statistic	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	 All Participants (N=30)
Any symptom				
n	16	12	47	75
Mean (SD)	1.8 (1.4)	2.1 (1.2)	1.7 (1.0)	1.8 (1.1)
Median	1.0	2.0	1.0	1.0
Min, Max	1, 6	1, 5	1, 4	1, 6
Any systemic symptom				
n	4	7	29	40
Mean (SD)	1.0 (0.0)	2.0 (1.5)	1.2 (0.6)	1.4 (0.8)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 5	1, 3	1, 5
Any local symptom				
n	12	5	18	35
Mean (SD)	2.1 (1.6)	2.2 (0.8)	2.3 (1.2)	2.2 (1.3)
Median	1.5	2.0	2.0	2.0
Min, Max	1, 6	1, 3	1, 4	1, 6

Abbreviations: Max = maximum; Min = minimum.
Source: Posttext Table 86.

7.2 Unsolicited Adverse Events

7.2.1 Overview of Unsolicited Adverse Events

Age Group: 18 to 55 Years

Overall, 44 (73%) participants reported at least 1 unsolicited AE and 20 (33%) participants reported unsolicited AEs related to mRNA-1273. The incidence of unsolicited AEs were similar among the vaccination groups. Thirteen (22%) participants reported at least 1 MAAE, none of which were related to mRNA-1273. Two participants (3%) experienced an AE leading to vaccine discontinuation, including 1 (2%) participant who experienced an AE related to mRNA-1273. One (2%) participant reported severe AEs related to mRNA-1273. No serious or fatal AEs were reported (Table 28).

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Age Group: 56 to 70 Years

Overall, 22 (73%) participants reported at least 1 unsolicited AE and 4 (13%) participants reported unsolicited AEs related to mRNA-1273. The incidence of unsolicited AEs were similar among the vaccination groups. Six (20%) participants reported at least 1 MAAE, none of which were related to mRNA-1273. One (3%) participant experienced an AE leading to vaccine discontinuation, and 2 (7%) participants reported severe AEs; none of these unsolicited AEs were related to mRNA-1273. No serious or fatal AEs were reported (Table 29).

Age Group: ≥ 71 Years

Overall, 23 (77%) participants reported at least 1 unsolicited AE and 7 (23%) participants reported unsolicited AEs related to mRNA-1273. The incidence of unsolicited AEs were similar among the vaccination groups. Five (17%) participants reported at least 1 MAAE, none of which were related to mRNA-1273. No participant experienced an AE leading to vaccine discontinuation, serious AE, fatal AE, or severe AE (Table 30).

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Table 28: Overall Summary of Unsolicited Adverse Events (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
	25 µg (N=15)	**50 µg (N=15)**	**100 µg (N=15)**	**250 µg (N=15)**	**All Participants (N=60)**
Unsolicited AEs regardless of relationship to study vaccine, n (%)					
All	12 (80)	10 (67)	11 (73)	11 (73)	44 (73)
Serious	–	–	–	–	–
Fatal	–	–	–	–	–
MAAE	4 (27)	3 (20)	2 (13)	4 (27)	13 (22)
NOCMC	–	–	–	–	–
Leading to discontinuation from study vaccine	1 (7)	–	–	1 (7)	2 (3)
Leading to discontinuation from study	–	–	–	–	–
Severe	–	–	–	1 (7)	1 (2)
Unsolicited AEs related to study vaccine, n (%)					
All	4 (27)	6 (40)	3 (20)	7 (47)	20 (33)
Serious	–	–	–	–	–
Fatal	–	–	–	–	–
MAAE	–	–	–	1 (7)	1 (2)
NOCMC	–	–	–	–	–
Leading to discontinuation from study vaccine	1 (7)	–	–	–	1 (2)
Leading to discontinuation from study	–	–	–	–	–
Severe	–	–	–	1 (7)	1 (2)

Abbreviations: AE = adverse event; MAAE = medically attended adverse events; NOCMC = new onset chronic medical conditions

Note: Participants were counted once for each category regardless of the number of events.

Source: Posttext Table 72.

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Table 29: Overall Summary of Unsolicited Adverse Events (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Unsolicited AEs regardless of relationship to study vaccine, n (%)				
All	7 (70)	7 (70)	8 (80)	22 (73)
Serious	–	–	–	–
Fatal	–	–	–	–
MAAE	2 (20)	3 (30)	1 (10)	6 (20)
NOCMC	1 (10)	–	–	1 (3)
Leading to discontinuation from study vaccine	–	–	1 (10)	1 (3)
Leading to discontinuation from study	–	–	–	–
Severe	–	1 (10)	1 (10)	2 (7)
Unsolicited AEs related to study vaccine, n (%)				
All	2 (20)	1 (10)	1 (10)	4 (13)
Serious	–	–	–	–
Fatal	–	–	–	–
MAAE	–	–	–	–
NOCMC	–	–	–	–
Leading to discontinuation from study vaccine	–	–	–	–
Leading to discontinuation from study	–	–	–	–
Severe	–	–	–	–

Abbreviations: AE = adverse event; MAAE = medically attended adverse events; NOCMC = new onset chronic medical conditions.

Participants were counted once for each category regardless of the number of events.

Source: Posttext Table 73.

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Table 30: Overall Summary of Unsolicited Adverse Events (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Unsolicited AEs regardless of relationship to study vaccine, n (%)				
All	9 (90)	6 (60)	8 (80)	23 (77)
Serious	–	–	–	–
Fatal	–	–	–	–
MAAE	1 (10)	1 (10)	3 (30)	5 (17)
NOCMC	–	–	–	–
Leading to discontinuation from study vaccine	–	–	–	–
Leading to discontinuation from study	–	–	–	–
Severe	–	–	–	–
Unsolicited AEs related to study vaccine, n (%)				
All	4 (40)	–	3 (30)	7 (23)
Serious	–	–	–	–
Fatal	–	–	–	–
MAAE	–	–	–	–
NOCMC	–	–	–	–
Leading to discontinuation from study vaccine	–	–	–	–
Leading to discontinuation from study	–	–	–	–
Severe	–	–	–	–

Abbreviations: AE = adverse event; MAAE = medically attended adverse events; NOCMC = new onset chronic medical conditions.

Participants were counted once for each category regardless of the number of events.

Source: Posttext Table 74.

7.2.2 Most Common Unsolicited Adverse Events

Age Group: 18 to 55 Years

As of data cutoff for this CSR, 44 (73%) participants reported 123 unsolicited AEs. The incidence of unsolicited AEs was similar among the vaccination groups (Table 31).

The most commonly reported (> 2 participants overall) unsolicited AEs were bradycardia, vomiting, vessel puncture site bruise, muscle strain, decreased appetite, and oropharyngeal

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pain (4 [7%] participants each) and injection site bruising, injection site pruritus, contusion, and skin abrasion (3 [5%] participants each).

No clinically relevant dose-dependent trends were noted in the incidence of unsolicited AEs among the vaccination groups.

Age Group: 56 to 70 Years

As of data cutoff for this CSR, 22 (73%) participants reported 32 unsolicited AEs. The incidence of unsolicited AEs was similar among the vaccination groups (Table 32). All unsolicited AEs were reported in ≤ 2 participants. No clinically relevant dose-dependent trend was noted in the incidence of unsolicited AEs among the vaccination groups.

Age Group: ≥ 71 Years

As of data cutoff for this CSR, 23 (77%) participants reported 59 unsolicited AEs. Although the incidence of unsolicited AEs was similar among the vaccination groups, the total number of unsolicited AEs were lower in the 50 µg vaccination group (7 AEs) than in the 25 µg and 100 µg vaccination groups (28 and 24 AEs, respectively) (Table 33).

The most commonly reported (> 2 participants overall) unsolicited AEs were skin abrasion (6 [20%] participants) and injection site bruising, vessel puncture site bruise, and dizziness (3 [10%] participants each).

No clinically relevant dose-dependent trends were noted in the incidence of unsolicited AEs among the vaccination groups.

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Table 31: Number and Percentage of Participants Reporting Unsolicited Adverse Events (All Participants 18 to 55 Years of Age)

System Organ Class Preferred Term	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Number of unsolicited AEs	31	24	28	40	123
Participants with any unsolicited AE, n (%)	12 (80)	10 (67)	11 (73)	11 (73)	44 (73)
Blood and lymphatic system disorders	–	1 (7)	–	–	1 (2)
Lymphadenopathy	–	1 (7)	–	–	1 (2)
Cardiac disorders	–	2 (13)	1 (7)	1 (7)	4 (7)
Bradycardia	–	2 (13)	1 (7)	1 (7)	4 (7)
Ear and labyrinth disorders	–	1 (7)	–	–	1 (2)
Vertigo	–	1 (7)	–	–	1 (2)
Eye disorders	–	–	1 (7)	1 (7)	2 (3)
Eye irritation	–	–	1 (7)	–	1 (2)
Scintillating scotoma	–	–	–	1 (7)	1 (2)
Gastrointestinal disorders	4 (27)	3 (20)	2 (13)	6 (40)	15 (25)
Abdominal discomfort	–	–	1 (7)	1 (7)	2 (3)
Abdominal pain	–	1 (7)	1 (7)	–	2 (3)
Abdominal pain upper	–	–	–	1 (7)	1 (2)
Anal fissure	–	–	–	1 (7)	1 (2)
Diarrhea	–	1 (7)	–	–	1 (2)
Dyspepsia	–	1 (7)	–	1 (7)	2 (3)
Feces discolored	–	–	1 (7)	–	1 (2)
Flatulence	1 (7)	–	–	–	1 (2)
Lip disorder	–	–	–	1 (7)	1 (2)
Tooth impacted	–	1 (7)	–	–	1 (2)
Vomiting	3 (20)	–	–	1 (7)	4 (7)

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System Organ Class Preferred Term	mRNA-1273 Dose Level 25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	All Participants (N=60)
General disorders and administration site conditions	4 (27)	3 (20)	4 (27)	3 (20)	14 (23)
Fatigue	1 (7)	–	–	–	1 (2)
Feeling jittery	–	–	1 (7)	–	1 (2)
Injection site bruising	–	–	3 (20)	–	3 (5)
Injection site erythema	–	–	–	2 (13)	2 (3)
Injection site irritation	1 (7)	–	–	-	1 (2)
Injection site pruritus	–	–	2 (13)	1 (7)	3 (5)
Malaise	–	–	–	1 (7)	1 (2)
Vaccination site movement impairment	–	1 (7)	–	–	1 (2)
Vessel puncture site bruise	2 (13)	1 (7)	–	1 (7)	4 (7)
Vessel puncture site hemorrhage	–	1 (7)	–	–	1 (2)
Immune system disorders	–	1 (7)	–	–	1 (2)
Seasonal allergy	–	1 (7)	–	–	1 (2)
Infections and infestations	2 (13)	1 (7)	2 (13)	2 (13)	7 (12)
Epididymitis	–	–	–	1 (7)	1 (2)
Gastroenteritis	–	–	1 (7)	–	1 (2)
Hordeolum	1 (7)	–	–	–	1 (2)
Infected cyst	–	–	1 (7)	–	1 (2)
Pustule	1 (7)	–	–	–	1 (2)
Upper respiratory tract infection	–	1 (7)	–	–	1 (2)
Urinary tract infection	–	–	–	1 (7)	1 (2)
Injury, poisoning and procedural complications	5 (33)	2 (13)	3 (20)	–	10 (17)
Contusion	3 (20)	–	–	–	3 (5)
Muscle strain	2 (13)	–	2 (13)	–	4 (7)
Skin abrasion	1 (7)	2 (13)	–	–	3 (5)
Skin laceration	1 (7)	–	–	–	1 (2)
Thermal burn	–	–	1 (7)	–	1 (2)
Wound	1 (7)	–	–	–	1 (2)
Investigations	–	1 (7)	1 (7)	–	2 (3)
Blood glucose decreased	–	1 (7)	–	–	1 (2)
Heart rate increased	–	–	1 (7)	–	1 (2)

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System Organ Class Preferred Term	mRNA-1273 Dose Level 25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	All Participants (N=60)
Metabolism and nutrition disorders	–	–	1 (7)	4 (27)	5 (8)
Decreased appetite	–	–	1 (7)	3 (20)	4 (7)
Hypoglycemia	–	–	–	1 (7)	1 (2)
Musculoskeletal and connective tissue disorders	2 (13)	2 (13)	1 (7)	4 (27)	9 (15)
Arthralgia	–	–	–	1 (7)	1 (2)
Muscle spasms	–	1 (7)	–	1 (7)	2 (3)
Muscle strain	–	–	–	1 (7)	1 (2)
Muscular weakness	1 (7)	–	–	–	1 (2)
Myalgia	–	1 (7)	–	–	1 (2)
Neck pain	–	–	1 (7)	–	1 (2)
Pain in extremity	–	–	–	1 (7)	1 (2)
Pain in jaw	1 (7)	–	–	–	1 (2)
Nervous system disorders	1 (7)	–	1 (7)	3 (20)	5 (8)
Dizziness	–	–	1 (7)	1 (7)	2 (3)
Headache	–	–	–	2 (13)	2 (3)
Presyncope	1 (7)	–	–	–	1 (2)
Syncope	–	–	–	1 (7)	1 (2)
Psychiatric disorders	–	–	1 (7)	1 (7)	2 (3)
Anxiety	–	–	–	1 (7)	1 (2)
Attention deficit hyperactivity disorder	–	–	1 (7)	–	1 (2)
Insomnia	–	–	-	1 (7)	1 (2)
Reproductive system and breast disorders	–	–	1 (7)	3 (20)	4 (7)
Breast pain	–	–	1 (7)	–	1 (2)
Vaginal hemorrhage	–	–	–	1 (7)	1 (2)
Vulvovaginal pruritus	–	–	–	2 (13)	2 (3)
Respiratory, thoracic and mediastinal disorders	2 (13)	2 (13)	3 (20)	1 (7)	8 (13)
Diaphragmatic spasm	–	–	1 (7)	–	1 (2)
Dyspnea exertional	1 (7)	–	–	–	1 (2)
Nasal congestion	–	1 (7)	1 (7)	–	2 (3)
Oropharyngeal pain	1 (7)	1 (7)	1 (7)	1 (7)	4 (7)
Upper airway cough syndrome	–	1 (7)	–	–	1 (2)

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System Organ Class Preferred Term	mRNA-1273 Dose Level				All Participants (N=60)
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	
Skin and subcutaneous tissue disorders	4 (27)	1 (7)	–	2 (13)	7 (12)
Dermatitis contact	1 (7)	–	–	–	1 (2)
Erythema	1 (7)	–	–	–	1 (2)
Hyperhidrosis	–	–	–	1 (7)	1 (2)
Night sweats	–	–	–	1 (7)	1 (2)
Petechiae	1 (7)	–	–	–	1 (2)
Rash	–	1 (7)	–	–	1 (2)
Urticaria	1 (7)	–	–	–	1 (2)
Vascular disorders	1 (7)	–	1 (7)	2 (13)	4 (7)
Hypertension	–	–	–	1 (7)	1 (2)
Hypotension	–	–	–	1 (7)	1 (2)
Systolic hypertension	1 (7)	–	–	–	1 (2)
Vasodilatation	–	–	1 (7)	–	1 (2)

Abbreviation: AE = adverse event.

A participant was counted once per preferred term.

Sources: Posttext Table 100, Posttext Table 101, Posttext Table 102, Posttext Table 103, Posttext Table 104, Posttext Table 113, Posttext Table 114, Posttext Table 115, Posttext Table 116, and Posttext Table 117.

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Table 32: Number and Percentage of Participants Reporting Unsolicited Adverse Events (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
System Organ Class **Preferred Term**	**25 µg (N=10)**	**50 µg (N=10)**	**100 µg (N=10)**	**All Participants (N=30)**
Number of unsolicited AEs	13	8	11	32
Participants with any unsolicited AE, n (%)	7 (70)	7 (70)	8 (80)	22 (73)
Cardiac disorders	–	2 (20)	–	2 (7)
Bradycardia	–	2 (20)	–	2 (7)
Ear and labyrinth disorders	–	–	1 (10)	1 (3)
Vertigo	–	–	1 (10)	1 (3)
Gastrointestinal disorders	–	1 (10)	1 (10)	2 (7)
Abdominal discomfort	–	1 (10)	–	1 (3)
Hemorrhoids	–	–	1 (10)	1 (3)
General disorders and administration site conditions	2 (20)	–	–	2 (7)
Injection site bruising	2 (20)	–	–	2 (7)
Infections and infestations	1 (10)	2 (20)	1 (10)	4 (13)
Onychomycosis	1 (10)	–	–	1 (3)
Paronychia	–	–	1 (10)	1 (3)
Urinary tract infection	–	1 (10)	–	1 (3)
Viral infection	–	1 (10)	–	1 (3)
Injury, poisoning and procedural complications	2 (20)	3 (30)	1 (10)	6 (20)
Arthropod sting	–	–	1 (10)	1 (3)
Exposure via inhalation	1 (10)	–	–	1 (3)
Limb injury	1 (10)	–	–	1 (3)
Muscle strain	–	1 (10)	–	1 (3)
Skin laceration	–	1 (10)	–	1 (3)
Tooth fracture	–	1 (10)	–	1 (3)
Investigations	1 (10)	–	–	1 (3)
Bone density decreased	1 (10)	–	–	1 (3)
Metabolism and nutrition disorders	1 (10)	–	1 (10)	2 (7)
Decreased appetite	1 (10)	–	–	1 (3)
Hypoglycemia	–	–	1 (10)	1 (3)
Musculoskeletal and connective tissue disorders	1 (10)	–	–	1 (3)
Pain in extremity	1 (10)	–	–	1 (3)

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System Organ Class Preferred Term	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	All Participants (N=30)
Nervous system disorders	2 (20)	–	1 (10)	3 (10)
Dizziness	–	–	1 (10)	1 (3)
Headache	1 (10)	–	–	1 (3)
Sciatica	1 (10)	–	–	1 (3)
Psychiatric disorders	1 (10)	–	–	1 (3)
Insomnia	1 (10)	–	–	1 (3)
Respiratory, thoracic and mediastinal disorders	1 (10)	–	2 (20)	3 (10)
Nasal congestion	–	–	1 (10)	1 (3)
Oropharyngeal pain	1 (10)	–	1 (10)	2 (7)
Skin and subcutaneous tissue disorders	–	–	1 (10)	1 (3)
Dermatitis contact	–	–	1 (10)	1 (3)
Rash maculo-papular	–	–	1 (10)	1 (3)
Vascular disorders	–	–	1 (10)	1 (3)
Systolic hypertension	–	–	1 (10)	1 (3)

Abbreviation: AE = adverse event.

A participant was counted once per preferred term.

Sources: Posttext Table 105, Posttext Table 106, Posttext Table 107, Posttext Table 108, Posttext Table 118, Posttext Table 119, Posttext Table 120, and Posttext Table 121.

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Table 33: Number and Percentage of Participants Reporting Unsolicited Adverse Events (All Participants ≥ 71 Years of Age)

System Organ Class Preferred Term	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	All Participants (N=30)
Number of unsolicited AEs	28	7	24	59
Participants with any unsolicited AE, n (%)	9 (90)	6 (60)	8 (80)	23 (77)
Cardiac disorders	1 (10)	–	1 (10)	2 (7)
Bradycardia	1 (10)	–	1 (10)	2 (7)
General disorders and administration site conditions	2 (20)	1 (10)	4 (40)	7 (23)
Energy increased	1 (10)	–	–	1 (3)
Fatigue	1 (10)	–	–	1 (3)
Injection site bruising	1 (10)	1 (10)	1 (10)	3 (10)
Injection site erythema	–	–	1 (10)	1 (3)
Injection site pruritus	1 (10)	–	–	1 (3)
Vessel puncture site bruise	–	–	3 (30)	3(10)
Infections and infestations	1 (10)	–	1 (10)	2 (7)
Pustule	1 (10)	–	–	1 (3)
Urinary tract infection	–	–	1 (10)	1 (3)
Injury, poisoning and procedural complications	5 (50)	2 (10)	4 (40)	11 (37)
Arthropod bite	1 (10)	1 (10)	–	2 (7)
Contusion	–	–	2 (20)	2 (7)
Injury	–	2 (20)	–	2 (7)
Limb injury	1 (10)	–	–	1 (3)
Procedural pain	1 (10)	–	–	1 (3)
Skin abrasion	3 (30)	–	3 (30)	6 (20)
Sunburn	1 (10)	–	–	1 (3)
Thermal burn	1 (10)	–	–	1 (3)
Tooth fracture	–	–	1 (10)	1 (3)
Musculoskeletal and connective tissue disorders	4 (40)	–	1 (10)	5 (17)
Arthritis	1 (10)	–	–	1 (3)
Joint swelling	1 (10)	–	–	1 (3)
Muscle tightness	1 (10)	–	–	1 (3)
Musculoskeletal chest pain	1 (10)	–	–	1 (3)
Myalgia	–	–	1 (10)	1 (3)

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System Organ Class Preferred Term	mRNA-1273 Dose Level 25 µg (N=10)	 50 µg (N=10)	 100 µg (N=10)	All Participants (N=30)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	–	–	1 (10)	1 (3)
Squamous cell carcinoma	–	–	1 (10)	1 (3)
Nervous system disorders	2 (20)	–	1 (10)	3 (10)
Dizziness	2 (20)	–	1 (10)	3 (10)
Visual field defect	1 (10)	–	–	1 (3)
Psychiatric disorders	2 (20)	–	–	2 (7)
Anxiety	1 (10)	–	–	1 (3)
Sleep disorder	1 (10)	–	–	1 (3)
Respiratory, thoracic and mediastinal disorders	–	1 (10)	–	1 (3)
Oropharyngeal pain	–	1 (10)	–	1 (3)
Skin and subcutaneous tissue disorders	3 (30)	–	4 (40)	7 (23)
Blister	–	–	1 (10)	1 (3)
Dermatitis	–	–	1 (10)	1 (3)
Dermatitis contact	–	–	1 (10)	1 (3)
Night sweats	1 (10)	–	1 (10)	2 (7)
Pruritus	1 (10)	–	–	1 (3)
Rash	–	–	1 (10)	1 (3)
Skin irritation	1 (10)	–	–	1 (3)
Vascular disorders	–	2 (20)	1 (10)	3 (10)
Hypertension	–	2 (20)	–	2 (7)
Systolic hypertension	–	–	1 (10)	1 (3)

Abbreviations: AE = adverse event; incl = including.

A participant was counted once per preferred term

Sources: Posttext Table 109, Posttext Table 110, Posttext Table 111, Posttext Table 112, Posttext Table 122, Posttext Table 123, Posttext Table 124, and Posttext Table 125.

7.2.3 Unsolicited Adverse Events by Maximum Intensity

Age Group: 18 to 55 Years

All unsolicited AEs (total 123) were mild (94 AEs in 38 [63%] participants) or moderate (27 AEs in 19 [32%] participants) in intensity except for 2 severe unsolicited AEs in 1 (2%) participant. A dose-dependent trend was observed in the severity of unsolicited AEs, with less participants reporting mild AEs and more participants reporting moderate AEs as the

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dose of mRNA-1273 increased (Table 34). All AEs resolved by the time of data cutoff except for 3 AEs (not related to mRNA-1273): hordeolum (25 µg, moderate), seasonal allergy (50 µg, mild), and insomnia (250 µg, mild) (Listing 12).

One participant in the 250 µg vaccination group reported severe dizziness and syncope on Day 1 after the second injection. Both events resolved on the same day and were deemed related to mRNA-1273 by the investigator (Listing 12).

Age Group: 56 to 70 Years

All unsolicited AEs (total 32) were of mild (17 AEs in 15 [50%] participants) or moderate (13 AEs in 9 [30%] participants) severity except for 2 severe events in 2 (7%) participants (Table 35). All AEs resolved by the time of data cutoff except for 4 AEs (not related to mRNA-1273): tooth fracture (50 µg, moderate), onychomycosis (25 µg, moderate), bone density decreased (25 µg moderate), and pain in extremity (25 µg, mild) (Listing 12).

One participant in the 50 µg vaccination group reported a severe AE of viral infection on Day 40 after the second injection. The event resolved after 27 days and was deemed not related to mRNA-1273 by the investigator. One participant in the 100 µg vaccination group reported a severe AE of hypoglycemia on Day 8 after the first injection. The event resolved after 5 days and was deemed not related to mRNA-1273 by the investigator. The participant continued in the study and received the second dose per protocol (Listing 12).

No clinically relevant dose-dependent trends were noted in the severity of unsolicited AEs among the vaccination groups.

Age Group: ≥ 71 Years

All unsolicited AEs (total 59) were mild (57 AEs in 23 [77%] participants) or moderate (2 AEs in 2 [7%] participants) in severity. The total number of mild AEs was lower in the 50 µg vaccination group than in the 25 µg and 100 µg vaccination groups, and moderate AEs were only reported in the 25 µg vaccination group. No severe AEs were reported (Table 36). All AEs resolved by the time of data cutoff except for 1 AE of bradycardia (100 µg, mild, not related to mRNA-1273) (Listing 12).

No clinically relevant dose-dependent trends were noted in the severity of unsolicited AEs among the vaccination groups.

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Table 34: Summary of Unsolicited Adverse Events by Severity (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	All Participants (N=60)
Total number of unsolicited AEs	31	24	28	40	123
Mild	28	20	22	24	94
Moderate	3	4	6	14	27
Severe	–	–	–	2	2
Participants with any unsolicited AE, n (%)	12 (80)	10 (67)	11 (73)	11 (73)	44 (73)
Mild	12 (80)	10 (67)	9 (60)	7 (47)	38 (63)
Moderate	3 (20)	3 (20)	5 (33)	8 (53)	19 (32)
Severe	–	–	–	1 (7)	1 (2)

Abbreviation: AE = adverse event.

Severity is the maximum severity reported after dosing for each participant.

Sources: Posttext Table 100, Posttext Table 101, Posttext Table 102, Posttext Table 103, Posttext Table 104, Posttext Table 113, Posttext Table 114, Posttext Table 115, Posttext Table 116, and Posttext Table 117.

Table 35: Summary of Unsolicited Adverse Events by Severity (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Total number of unsolicited AEs	13	8	11	32
Mild	7	4	6	17
Moderate	6	3	4	13
Severe	–	1	1	2
Participants with any unsolicited AE, n (%)	7 (70)	7 (70)	8 (80)	22 (73)
Mild	6 (60)	4 (40)	5 (50)	15 (50)
Moderate	4 (40)	3 (30)	2 (20)	9 (30)
Severe	–	1 (10)	1 (10)	2 (7)

Abbreviation: AE = adverse event.

Severity is the maximum severity reported after dosing for each participant.

Sources: Posttext Table 105, Posttext Table 106, Posttext Table 107, Posttext Table 108, Posttext Table 118, Posttext Table 119, Posttext Table 120, and Posttext Table 121.

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Table 36: Summary of Unsolicited Adverse Events by Severity (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Total number of unsolicited AEs	28	7	24	59
Mild	26	7	24	57
Moderate	2	–	–	2
Severe	–	–	–	–
Participants with any unsolicited AE, n (%)	9 (90)	6 (60)	8 (80)	23 (77)
Mild	9 (90)	6 (60)	8 (80)	23 (77)
Moderate	2 (20)	–	–	2 (7)
Severe	–	–	–	–

Abbreviation: AE = adverse event.

Severity is the maximum severity reported after dosing for each participant.

Sources: Posttext Table 109, Posttext Table 110, Posttext Table 111, Posttext Table 112, Posttext Table 122, Posttext Table 123, Posttext Table 124, and Posttext Table 125.

7.2.4 Adverse Events by Relationship to Study Vaccine

Age Group: 18 to 55 Years

Of the 123 unsolicited AEs reported in 44 (73%) participants, 41 AEs in 20 (33%) participants were deemed related to mRNA-1273 (Table 37). A trend toward a dose-dependent increase in the total number of AEs related to mRNA-1273 was noted; however, no such trend was noted in the number of participants reporting unsolicited AEs related to mRNA-1273. Notably, the number of participants with unsolicited AEs related to mRNA-1273 was lowest in the 100 µg vaccination group.

The most commonly reported (> 2 participants overall) unsolicited AEs related to mRNA-1273 were decreased appetite (4 [7%] participants) and injection site pruritus (3 [5%] participants) (Posttext Table 117).

The only severe AEs that were related to mRNA-1273 occurred in 1 participant in the 250 µg vaccination group, who reported 2 severe AEs (dizziness and syncope) (Section 7.2.3). All unsolicited AEs related to mRNA-1273 resolved.

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Of note, 1 participant in the 25 µg vaccination group reported mild urticaria (hives on lower extremities) related to mRNA-1273 that led to treatment withdrawal (Section 7.3.3.1).

Age Group: 56 to 70 Years

Of the 32 unsolicited AEs reported in 22 (73%) participants, only 4 AEs in 4 (13%) participants were deemed related to mRNA-1273 (Table 38): moderate decreased appetite (25 µg, Day 1 after the second injection), mild insomnia (25 µg, the day of the second injection), moderate abdominal discomfort (50 µg, Day 4 after the first injection), and mild vertigo (100 µg, Day 1 after the second injection). All events resolved. (Listing 12).

Age Group: ≥ 71 Years

Of the 59 unsolicited AEs reported in 23 (77%) participants, 14 AEs in 7 (23%) participants were deemed related to mRNA-1273 (Table 39).

Four participants in the 25 µg vaccination group reported 11 related AEs: mild dizziness (the day of the first injection), mild night sweats (Day 2 after the first injection), and mild anxiety (Day 4 after the first injection) in 1 participant; mild energy increased (the day of the first injection and the day of the second injection), mild visual field defect (the day of the second injection), mild injection site pruritus (Day 2 after the second injection), and mild fatigue (Day 11 after the second injection) in 1 participant; mild pruritus (the day of the first injection) in 1 participant; and mild sleep disorder (the day of the first injection and Day 1 after the second injection) in 1 participant. Three participants in the 100 µg vaccination group reported 3 related AEs: mild injection site erythema (Day 9 after the first injection), mild dizziness (the day of the second injection), and mild night sweats (Day 1 after the second injection). All events resolved (Listing 12).

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Table 37: Summary of Unsolicited Adverse Events by Relationship (All Participants 18 to 55 Years of Age)

	mRNA-1273 Dose Level				
	25 µg (N=15)	50 µg (N=15)	100 µg (N=15)	250 µg (N=15)	All Participants (N=60)
Total number of unsolicited AEs	31	24	28	40	123
Not related	26	17	18	21	82
Related	5	7	10	19	41
Participants with any unsolicited AE, n (%)	12 (80)	10 (67)	11 (73)	11 (73)	44 (73)
Not related	11 (73)	8 (53)	9 (60)	8 (53)	36 (60)
Related	4 (27)	6 (40)	3 (20)	7 (47)	20 (33)

Abbreviation: AE = adverse event.

Sources: Posttext Table 100, Posttext Table 101, Posttext Table 102, Posttext Table 103, Posttext Table 104, Posttext Table 113, Posttext Table 114, Posttext Table 115, Posttext Table 116, and Posttext Table 117.

Table 38: Summary of Unsolicited Adverse Events by Relationship (All Participants 56 to 70 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Total number of unsolicited AEs	13	8	11	32
Not related	11	7	10	28
Related	2	1	1	4
Participants with any unsolicited AE, n (%)	7 (70)	7 (70)	8 (80)	22 (73)
Not related	5 (50)	6 (60)	8 (80)	19 (63)
Related	2 (20)	1 (10)	1 (10)	4 (13)

Abbreviation: AE = adverse event.

Sources: Posttext Table 105, Posttext Table 106, Posttext Table 107, Posttext Table 108, Posttext Table 118, Posttext Table 119, Posttext Table 120, and Posttext Table 121.

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Table 39: Summary of Unsolicited Adverse Events by Relationship (All Participants ≥ 71 Years of Age)

	mRNA-1273 Dose Level			
	25 µg (N=10)	50 µg (N=10)	100 µg (N=10)	All Participants (N=30)
Total number of unsolicited AEs	28	7	24	59
Not related	17	7	21	45
Related	11	-	3	14
Participants with any unsolicited AE, n (%)	9 (90)	6 (60)	8 (80)	23 (77)
Not related	7 (70)	6 (60)	7 (70)	20 (67)
Related	4 (40)	-	3 (30)	7 (23)

Abbreviation: AE = adverse event.

Sources: Posttext Table 109, Posttext Table 110, Posttext Table 111, Posttext Table 112, Posttext Table 122, Posttext Table 123, Posttext Table 124, and Posttext Table 125.

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

7.3.1 Deaths

At the time of the data cutoff for this CSR, no deaths had occurred during the study.

7.3.2 Other Serious Adverse Events

At the time of the data cutoff for this CSR, no SAEs had occurred during the study (Posttext Table 126).

7.3.3 Other Clinically Meaningful Adverse Events

7.3.3.1 Adverse Events Leading to Discontinuation

As of the data cutoff for this CSR, 4 participants had discontinued the vaccine on the study; 3 of those participants discontinued due to an AE.

One participant in the 25 µg vaccination group (age group: 18 to 55 years) reported mild urticaria (hives on lower extremities) on Day 5 after the first injection. The event was deemed related to mRNA-1273 by the investigator and resolved within 1 day (Listing 2 and Listing 12).

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One participant in the 250 µg vaccination group (age group: 18 to 55 years) reported mild oropharyngeal pain (sore throat) on Day 24 after the first injection. The event was deemed not related to mRNA-1273 by the investigator and resolved within 3 days (Listing 2 and Listing 12).

One participant in the 100 µg vaccination group (age group: 56 to 70 years) reported moderate rash maculo-papular (maculopapular rash) on Day 9 after the first injection. The event was deemed not related to mRNA-1273 by the investigator and resolved within 21 days (Listing 2 and Listing 12).

7.3.3.2 Adverse Events of Special Interest

As of the database cutoff for this CSR, 33 MAAEs have been reported in 24 participants (Posttext Table 127). All MAAEs were deemed not related to mRNA-1273 except for moderate abdominal discomfort reported by 1 participant in the 250 µg vaccination group (age group: 18 to 55 years) on Day 26 after the second injection. The event was deemed related to mRNA-1273 by the investigator and resolved within 10 days (Listing 12).

One participant in the 25 µg vaccination group (age group: 56 to 70 years) reported moderate bone density decreased on Day 28 after the second injection; the event was captured as both an NOCMC and MAAE. The event was deemed not related to mRNA-1273 by the investigator and was resolving by the time of data cutoff (Listing 12).

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7.4 Clinical Laboratory Evaluation

7.4.1 Clinical Laboratory Values Over Time

Overall, no notable trends were observed for any vaccination group in laboratory test result values for chemistry (Posttext Table 141, Posttext Table 142, Posttext Table 143, Posttext Table 144, Posttext Table 145, and Posttext Table 146) and hematology (Posttext Table 154, Posttext Table 155, and Posttext Table 156) parameters. No trends were observed among the age group or vaccination group and the severity of events in the chemistry test results (Posttext Table 128, Posttext Table 129, Posttext Table 130, Posttext Table 131, Posttext Table 132, Posttext Table 133, and Posttext Table 134) and hematology test results (Posttext Table 147, Posttext Table 148, Posttext Table 149, and Posttext Table 150).

Age Group: 18 to 55 Years

After vaccination 7 (12%) participants experienced an abnormal chemistry result with a maximum severity of mild, 1 (2%) participant experienced an abnormal chemistry result with a maximum severity of moderate, and 1 (2%) participant experienced an abnormal chemistry result with a maximum severity of severe. Three (5%) participants experienced an abnormal ALT result with a maximum severity of mild, 1 (2%) participant experienced an abnormal AST result with a maximum severity of mild, 2 (3%) participants experienced an abnormal T. Bili result with a maximum severity of mild, and 1 (2%) participant experienced an abnormal T. Bili result with a maximum severity of moderate. One (2%) participant experienced an abnormal serum lipase result with a maximum severity of mild and 1 (2%) participant experienced an abnormal serum lipase result with a maximum severity of severe.

After vaccination, 49 (82%) participants experienced an abnormal hematology result with a maximum severity of mild and 6 (10%) participants experienced an abnormal hematology result with a maximum severity of moderate. Forty-eight (80%) participants experienced an abnormal Hgb results with a maximum severity of mild and 6 (10%) participants experienced an abnormal Hgb result with maximum severity of moderate. Seven (12%) participants experienced an abnormal WBC count result with a maximum severity of mild. The majority of the abnormal hematology results were due to changes relative to the baseline values; most of the post-vaccination values were within the normal range.

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Age Group: 56 to 70 Years

Two (7%) participants experienced an abnormal chemistry result after vaccination, with a maximum severity of mild: abnormal AST and abnormal serum lipase level in 1 (3%) participant each.

After vaccination, 26 (87%) participants experienced an abnormal hematology result with a maximum severity of mild, 2 (7%) participants experienced an abnormal hematology result with a maximum severity of moderate, and 2 (7%) participants experienced an abnormal hematology result with a maximum severity of severe; all abnormal results were for Hgb levels.

Age Group: ≥ 71 Years

After vaccination, 2 (7%) participants experienced an abnormal chemistry result with a maximum severity of mild, and 1 (3%) participant experienced an abnormal chemistry result with a maximum severity of severe; all 3 participants' abnormal results were for serum lipase levels.

After vaccination, 28 (93%) participants experienced an abnormal hematology result with a maximum severity of mild: 27 (90%) participants experienced mild abnormal Hgb results, 4 (13%) participants experienced mild abnormal WBC count results, and 2 (7%) participants experienced mild abnormal PLT counts.

7.4.2 Evaluation of Individual Laboratory Parameters

7.4.2.1 Individual Participant Changes by Vaccination Group

Individual shifts from normal at baseline to abnormal postbaseline for chemistry (Posttext Table 135, Posttext Table 136, Posttext Table 137, Posttext Table 138, Posttext Table 139, and Posttext Table 140) and hematology (Posttext Table 151, Posttext Table 152, and Posttext Table 153) parameters were generally mild. Individual shifts in laboratory parameters from normal at baseline to moderate abnormality at postbaseline visits are as follows:

- T. Bili: 1 participant in the 18 to 55 years of age group (25 µg vaccination group)
- Serum lipase: 1 participant in the 18 to 55 years of age group (250 µg vaccination group)
- Hgb: Six participants in the 18 to 55 years of age group (3 participants each in the 50 µg and 250 µg vaccination groups) and 4 participants in the 56 to 70 years of age group (3 participants in the 25 µg vaccination group and 1 participant in 100 µg vaccination group)

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The participants who experienced severe abnormalities in laboratory parameters are described in Section 7.4.2.2.

7.4.2.2 Individual Clinically Meaningful Abnormalities by Vaccination Group

For chemistry (Listing 13) and hematology (Listing 14) laboratory test results, 5 instances of severe abnormalities were reported in 4 participants. All except 1 abnormality (serum lipase in a participant in the 18 to 55 years of age group [250 µg vaccination group]) were considered not related to mRNA-1273 and no abnormality led to a dose change or participant discontinuation from the study.

- In one participant in the ≥ 71 years of age group (50 µg vaccination group), serum lipase was 181.0 U/L on Day 1 (baseline assessment) and increased to 336.0 U/L on Day 7. Both of these values were considered abnormal (not related to mRNA-1273).

- In one participant in the 18 to 55 years of age group (250 µg vaccination group), serum lipase increased from 62.0 U/L on Day 1 to 240.0 U/L on Day 56 (related to mRNA-1273).

- In one participant in the 56 to 70 years of age group (25 µg vaccination group), Hgb decreased from 16.8 g/dL on Day 1 to 14.1 g/dL on Day 29 (not related to mRNA-1273).

- In one participant in the 56 to 70 years of age group (100 µg vaccination group), Hgb decreased from 14.4 g/dL on Day 1 to 12.3 g/dL on Day 114 (not related to mRNA-1273).

7.5 Vital Signs, Physical Examination, and Other Observations Related to Safety

7.5.1 Vital Signs

Overall, no notable trends were observed in vital sign results for any age group or vaccination group (Listing 15), and no trend was observed among age group or vaccination group and the severity of events for any parameter (Posttext Table 157, Posttext Table 162, and Posttext Table 167), systolic BP (Posttext Table 158, Posttext Table 163, and Posttext Table 168), diastolic BP (Posttext Table 159, Posttext Table 164, and Posttext Table 169), pulse rate (Posttext Table 160, Posttext Table 165, and Posttext Table 170), or temperature (Posttext Table 161, Posttext Table 166, and Posttext Table 171).

Most of the abnormalities in vital signs postbaseline were mild. Three participants had moderate vital sign abnormalities post vaccination: 1 participant in the 18 to 55 years of age group (250 µg

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vaccination group) had a pulse rate of 48 bpm (moderate) on Day 113, 1 participant in the 56 to 70 years of age group (25 µg vaccination group) had systolic BP of 152 mm Hg (moderate) on Day 113, and 1 participant in the 56 to 70 years of age group (100 µg vaccination group) had systolic BP of 153 mm Hg (moderate) on Day 15 (Listing 15).

7.5.1.1 Vital Signs Reported as Adverse Events

Age Group: 18 to 55 Years

Abnormal vital sign measurements observed after vaccination were reported as AEs for 4 participants in the 18 to 55 years of age group. One participant in the 25 µg vaccination group had systolic hypertension on Day 28 after the first injection that resolved within 8 days, 1 participant in the 250 µg vaccination group had hypertension on Day 6 after the first injection that resolved the same day, 1 participant in the 250 µg vaccination group had hypotension on Day 28 after the first injection that resolved within 15 days, and 1 participant in the 100 µg vaccination group had heart rate increased on Day 13 after the first injection that resolved within 14 days. All events were mild in severity and none were related to mRNA-1273 (Listing 12).

Age Group: 56 to 70 Years

Abnormal vital sign measurements observed after vaccination were reported as AEs for 1 participant in the 56 to 70 years of age group (100 µg vaccination group). The participant had mild systolic hypertension on Day 14 after the first injection that was not related to mRNA-1273 and resolved within 15 days (Listing 12).

Age Group: ≥ 71 Years

Abnormal vital sign measurements observed after vaccination were reported as AEs for 3 participants in the ≥ 71 years of age group. One participant in the 50 µg vaccination group had hypertension on Day 0 after the first injection that resolved within 6 days, 1 participant in the 50 µg vaccination group had hypertension on Day 0 after the second injection that resolved within 28 days, and 1 participant in the 100 µg vaccination group had systolic hypertension on Day 14 after the second injection that resolved within 14 days. All events were mild in severity and none were related to mRNA-1273 (Listing 12).

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7.5.2 Physical Examination

Changes from baseline in physical examination findings were collected and reported as AEs. Overall, abnormal physical findings were reported as unsolicited AEs in 8 participants and related to either the skin or musculoskeletal system (Listing 16).

7.6 Pregnancies

As of the data cutoff for this CSR, no pregnancies have been reported (Listing 18).

7.7 Safety Conclusions

Note: For consistency across the mRNA-1273 program, solicited AEs were referred to as solicited ARs when summarized in the results.

- Overall, mRNA-1273 demonstrated an acceptable safety profile.
- No serious AEs or AEs leading to study discontinuation were noted.
- Most of the solicited ARs were mild or moderate. In the 18 to 55 years of age group, severe solicited ARs predominantly occurred at the highest dose (250 µg): 4 participants in the 250 µg versus 1 participant each in the 50 µg and 100 µg vaccination groups. Additionally, severe solicited ARs were reported in 1 participant each in the 25 µg and 50 µg vaccination groups (age group: 56 to 70 years) and 1 participant in the 100 µg vaccination group (age group: ≥ 71 years).
- The most commonly reported solicited systemic ARs after any dose across all age groups were fatigue (captured in the memory aid as tiredness), headache, myalgia (captured in the memory aid as body aches/muscle pain), and feverishness (captured in the memory aid as chills). The incidence of solicited systemic ARs was higher after the second injection than after the first injection. Overall, fatigue and headache were the most commonly reported solicited systemic ARs after the first injection; fatigue, headache, myalgia, and feverishness were the most commonly reported solicited systemic ARs after the second injection. Notably, in the 18 to 55 years of age group, the incidence of arthralgia, feverishness, headache, myalgia, and nausea increased by more than 2-fold after the second injection compared with the incidence after the first injection, and no participant reported fever after the first injection, but 15 (26%) participants reported fever after the second injection. In all age groups, severe solicited systemic ARs occurred only after the second injection.

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- Overall, injection site pain was the most commonly reported solicited local AR. The incidence of the solicited local ARs was similar after the first injection and after the second injection.

- Most of solicited ARs had an onset within 2 days after vaccination, and the median durations of solicited ARs were 1 to 2 days. Notably, all severe solicited ARs resolved within 1 to 2 days.

- The incidence of unsolicited AEs was similar among vaccination groups across all age groups. Most unsolicited AEs were mild or moderate in severity.

- All unsolicited AEs related to mRNA-1273 were mild or moderate in severity, except for 2 severe AEs (dizziness and syncope, both occurring on Day 1 after the second injection) in 1 participant in the 18 to 55 years of age group (250 µg vaccination group). All AEs related to mRNA-1273 resolved.

- Adverse events leading to treatment discontinuation were reported in 3 participants. Of these, 1 mild AE of urticaria (25 µg vaccination group, age group: 18 to 55 years) was related to mRNA-1273.

- A total of 33 MAAEs were reported in 24 participants. All MAAEs were considered not related to mRNA-1273, except 1 MAAE (moderate abdominal discomfort) in 1 participant in the 18 to 55 years of age group (250 µg vaccination group). One AE (moderate bone density decreased) in one participant in the 56 to 70 years of age group (25 µg vaccination group) was captured as both an MAAE and NOCMC and was not related to mRNA-1273.

- Overall, no notable trends were observed in the hematology and chemistry laboratory test results for any vaccination group, and no trends were observed among dose level and the severity of events.

- One severe abnormal laboratory result (serum lipase; 18 to 55 years of age group, 250 µg vaccination group) was considered related to mRNA-1273.

- No notable trends were observed in vital sign results and physical examination findings for any age group or vaccination group, and no trend was observed among dose levels and the severity of events.

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- Based on the safety findings that a higher incidence of severe solicited ARs was noted in the 250 µg group, the only participant reporting severe unsolicited AEs related to mRNA-1273 received 250 µg of mRNA-1273, and the only severe clinically meaningful laboratory abnormality (increased serum lipase) related to mRNA-1273 was noted in the 250 µg group; the 100 µg, 50 µg, and 25 µg dose levels can be considered to have a more acceptable safety profile than the 250 µg dose level. This was the rationale for not continuing to evaluate the 250 µg dose in the older age cohorts.

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8 Pharmacokinetic Results

Not applicable.

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9 Pharmacodynamic Results

Not applicable.

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10 Immunogenicity Results

Humoral immunogenicity assessments included ELISA to quantify the binding antibody IgG responses to full-length S-2P protein containing an Asp (D) residue at position 614 (Wuhan-1 strain sequence) and to the RBD, located in the S1 subunit. A SARS-CoV-2 native S-bearing pseudotyped lentivirus reporter single-round-of-infection neutralization assay (PsVNA) was used to assess vaccine-induced neutralizing activity against the 614D and 614-Gly (614G) polymorphic variants. Additional live-virus neutralization assessments were performed and included the FRNT-mNG, which used recombinant SARS-CoV-2 expressing the fluorescent reporter gene mNeonGreen, and a SARS-CoV-2 PRNT, which used wild-type SARS-CoV-2 virus.

A convalescent sera control panel from 41 COVID-19 patients who had donated serum after recovering from acute infection was used as a comparator for the ELISA and PsVNA vaccine-induced responses and to establish correlations across the ELISA (S-2P and RBD) and the serum antibody neutralization assays (PsVNA and FRNT-mNG). The severity of COVID-19 illness was known for 38 convalescent sera controls and was classified as mild in 63% of the patients, moderate in 22% patients, and severe (defined as hospitalization requiring intensive care, ventilation, or both) in 15% patients. Time since diagnosis (onset of symptoms or positive polymerase chain reaction test) ranged from 23 to 54 days (median 34 days) for the convalescent sera control panel.

An intracellular cytokine stimulation assay was used to evaluate T-cell responses elicited by the mRNA-1273 vaccine in PBMC samples following stimulation with S1 and S2 subunit-specific peptide pools.

10.1 IgG ELISA

10.1.1 SARS-CoV-2 S-2P–Specific Binding Antibody Endpoint Titers

The S-2P ELISA results demonstrated a robust antibody response after each dose. As shown in Figure 16, the S-2P ELISA GMT values showed a substantial increase after dosing, with peaks seen at Day 36 or Day 43 for most age groups and mRNA-1273 dose levels. In general, the S-2P ELISA GMT values decreased by Day 119 but remained higher than the Day 29 (prior to the second injection) values (Posttext Table 15, Posttext Table 16, and Posttext Table 17). In general, dose-dependent antibody responses to the first injection and second injection were observed. The S-2P ELISA GMT values were generally numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups across all age groups. The S-2P ELISA GMT values in the 250 µg vaccination group were numerically higher than those in the 25 µg, 50 µg, and 100 µg vaccination groups in the 18 to 55 years of age group. For all age groups and mRNA-1273 dose

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levels, the S-2P ELISA GMT values for Day 43 and Day 57 exceeded the median GMT values for the convalescent sera control group. For the 100 µg and 250 µg mRNA-1273 doses, the S-2P ELISA GMT values at Day 119 were numerically higher than that for the convalescent sera control group.

The S-2P ELISA GMFR results also showed robust responses after each injection across all age groups, and the seroconversion criteria of a 4-fold increase in endpoint titers compared with baseline were met at a majority of the postbaseline visits (Posttext Table 60, Posttext Table 61, and Posttext Table 62). For the 100 µg mRNA-1273 dose, the seroconversion criteria were met at all postbaseline visits through Day 119 across all age groups.

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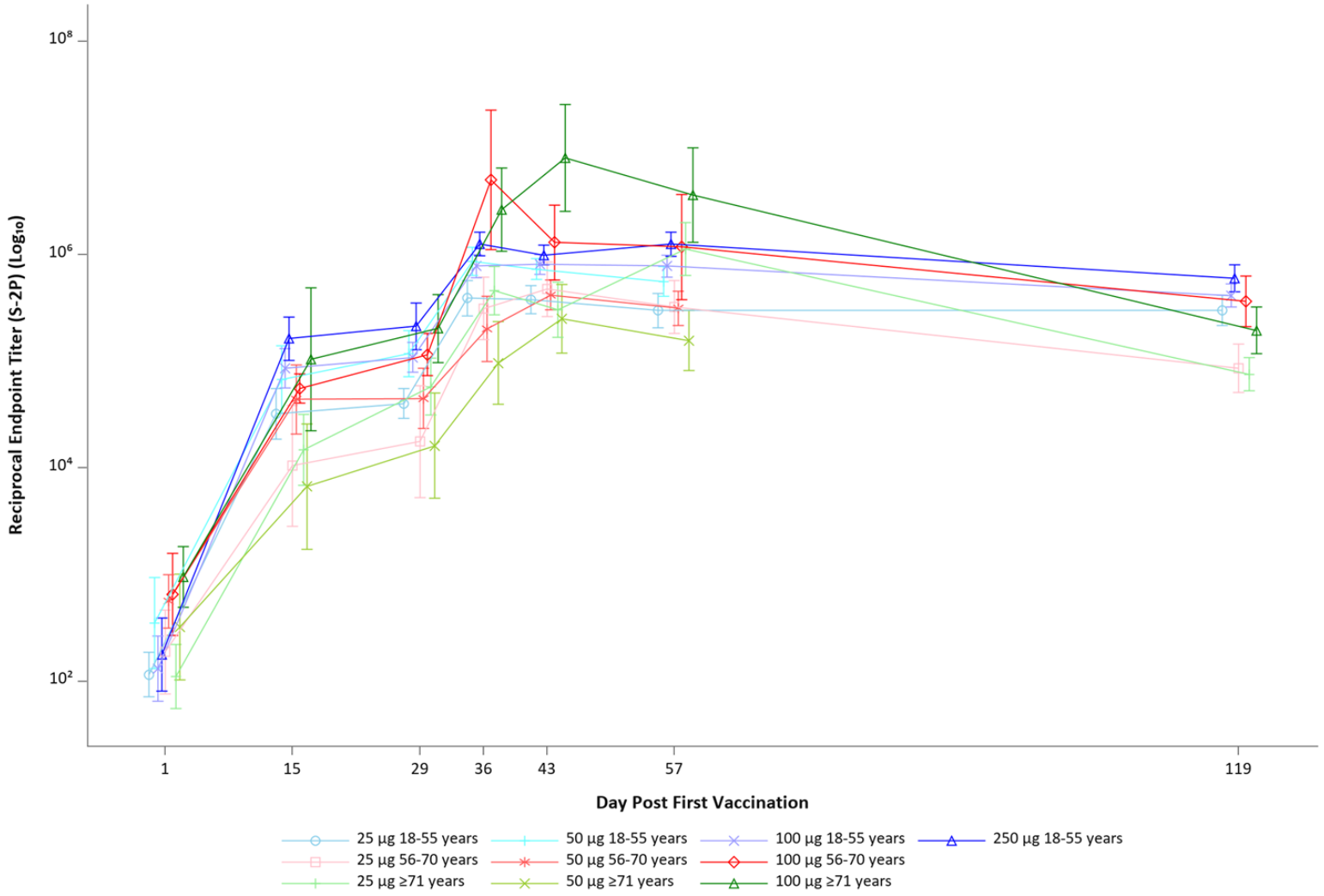
Figure 16: Geometric Mean Endpoint Titer Values by Time Point and Vaccination Group – S-2P



Abbreviation: S-2P = spike protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein into a prefusion conformation.
Source: Posttext Figure 14.

10.1.2 SARS-CoV-2 RBD–Specific Binding Antibody Endpoint Titers

The RBD ELISA results demonstrated a robust antibody response after each dose. As shown in Figure 17, the RBD ELISA GMT values showed a substantial increase after dosing, with peaks seen from Day 36 to Day 43 for most age groups and mRNA-1273 dose levels. The RBD ELISA GMT values decreased by Day 119 but remained higher than the Day 29 (prior to the second injection) values (Posttext Table 18, Posttext Table 19, and Posttext Table 20). In general, dose-dependent antibody responses to the first injection and second injection were observed. The RBD ELISA GMT values were numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups in the 56 to 70 years and ≥ 71 years of age groups. For all age groups and mRNA-1273 dose levels, the RBD ELISA GMT values for Day 36 and beyond exceeded the median GMT values for the convalescent sera control group.

Like S-2P ELISA GMFR results, the RBD ELISA GMFR results also showed robust responses after each injection across all age groups, and the seroconversion criteria of a 4-fold increase in endpoint titers compared with baseline were met at a majority of postbaseline visits (Posttext Table 63, Posttext Table 64, and Posttext Table 65) through Day 119.

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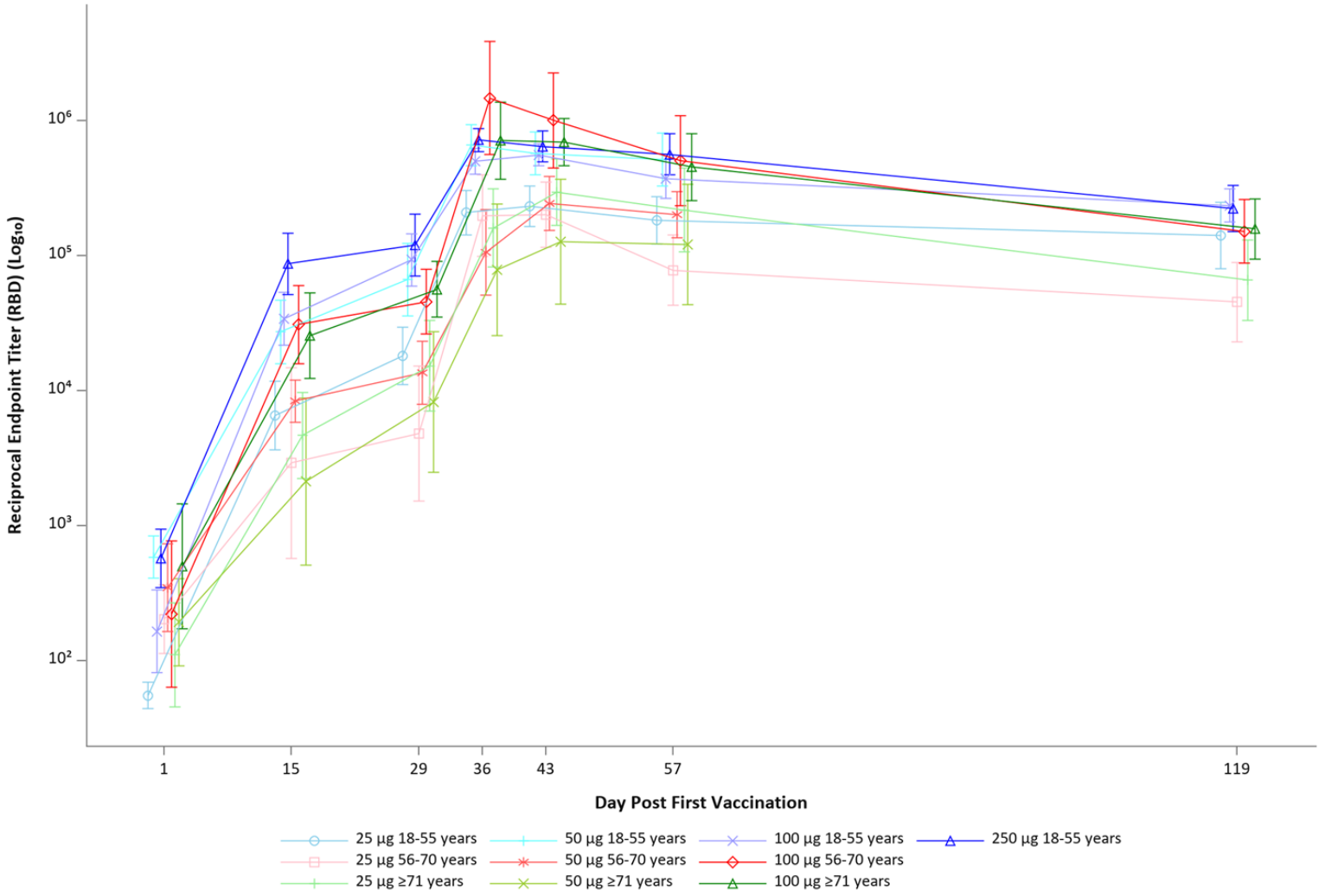
Figure 17: Geometric Mean Endpoint Titer Values by Time Point and Vaccination Group – RBD



Abbreviation: RBD = receptor binding domain
Source: Posttext Figure 15.

10.2 SARS-CoV-2 Pseudovirus Neutralization Assay (PsVNA)

The PsVNA GM neutralizing ID_{50} (Figure 18) and ID_{80} (Figure 19) titers for the 614D variant were undetectable prior to the first injection, marginally increased after the first injection, and substantially increased after the second injection. Titers peaked from Day 36 to Day 57 for most age groups and mRNA-1273 dose levels. The PsVNA GM titers had declined by Day 119 but remained higher than the Day 29 (prior to the second injection) values (Posttext Table 27, Posttext Table 28, and Posttext Table 29 for ID_{50} and Posttext Table 30, Posttext Table 31, and Posttext Table 32 for ID_{80}). The PsVNA GM titers (ID_{50} and ID_{80}) after 2 injections were similar at Day 57 among the 50 µg, 100 µg, and 250 µg vaccination groups in the 18 to 55 years of age group. In both the 56 to 70 and ≥ 71 years of age groups, the PsVNA GM titers (ID_{50} and ID_{80}) after 2 injections were numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups. Notably, for the 100 µg mRNA-1273 vaccination group, the ID_{50} and ID_{80} GM titers from Day 36 through Day 119 were similar to (≥ 71 years of age group) or exceeded (18 to 55 and 56 to 70 years of age groups) the GM titers from the convalescent sera control group.

Robust neutralizing antibody responses to the 614G variant were also observed at Day 43 for the 100 µg vaccination group regardless of age (Posttext Table 33 for ID_{50} and Posttext Table 34 for ID_{80}). Of note, the PsVNA 614G GM titers at Day 43 were substantially higher across age groups than those observed for the 614D variant, but trends for the 2 variants were similar.

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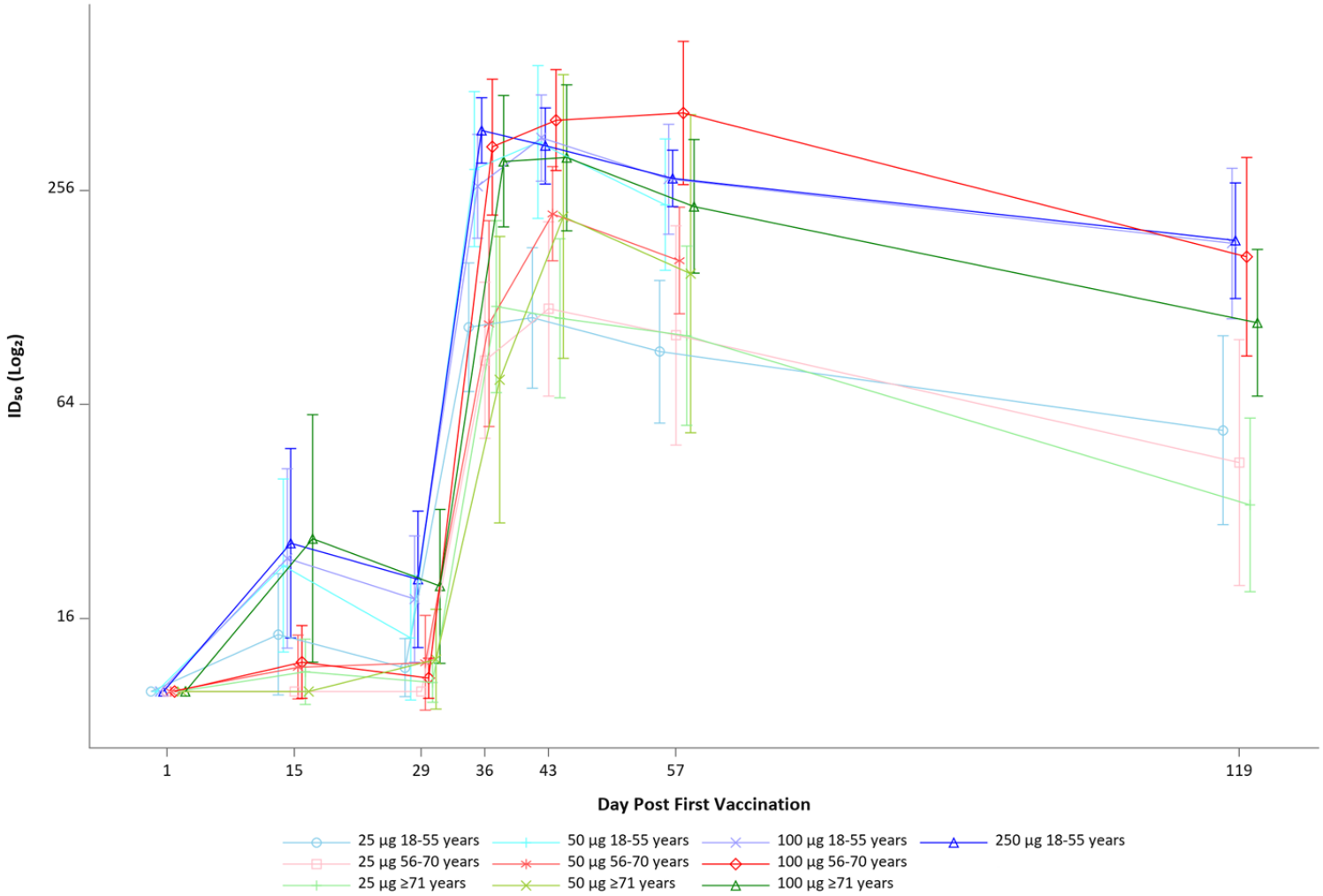
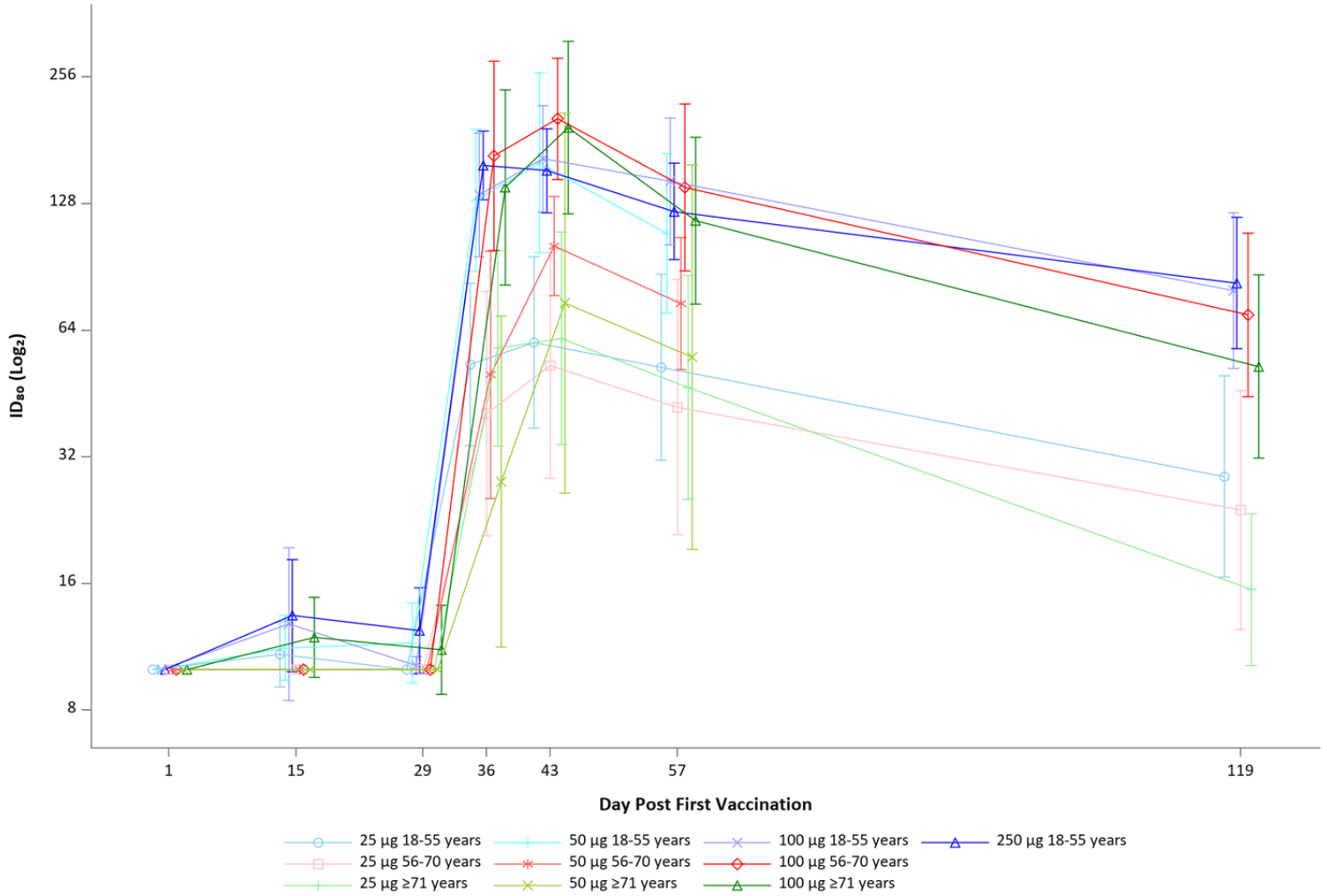
Figure 18: PsVNA Geometric Mean by Time Point and Vaccination Group – ID_{50}



Abbreviations: PsVNA = pseudovirus neutralization assay; ID_{50} = serum dilution required to achieve 50% neutralization
Source: Posttext Figure 18.

Figure 19: PsVNA Geometric Mean by Time Point and Vaccination Group – ID_{80}



Abbreviations: PsVNA = pseudovirus neutralization assay; ID_{80} = serum dilution required to achieve 80% neutralization
Source: Posttext Figure 19.

10.3 Wild-Type SARS-CoV-2 Plaque Reduction Neutralization Test (PRNT)

As shown in Figure 20, the $PRNT_{80}$ GM neutralizing titers were undetectable prior to the first injection but were readily detectable and increased substantially after the second injection. For the 100 µg vaccination group, neutralizing titers persisted through Day 119 with a modest decline from Day 43 levels in all age groups (Posttext Table 35, Posttext Table 36, and Posttext Table 37).

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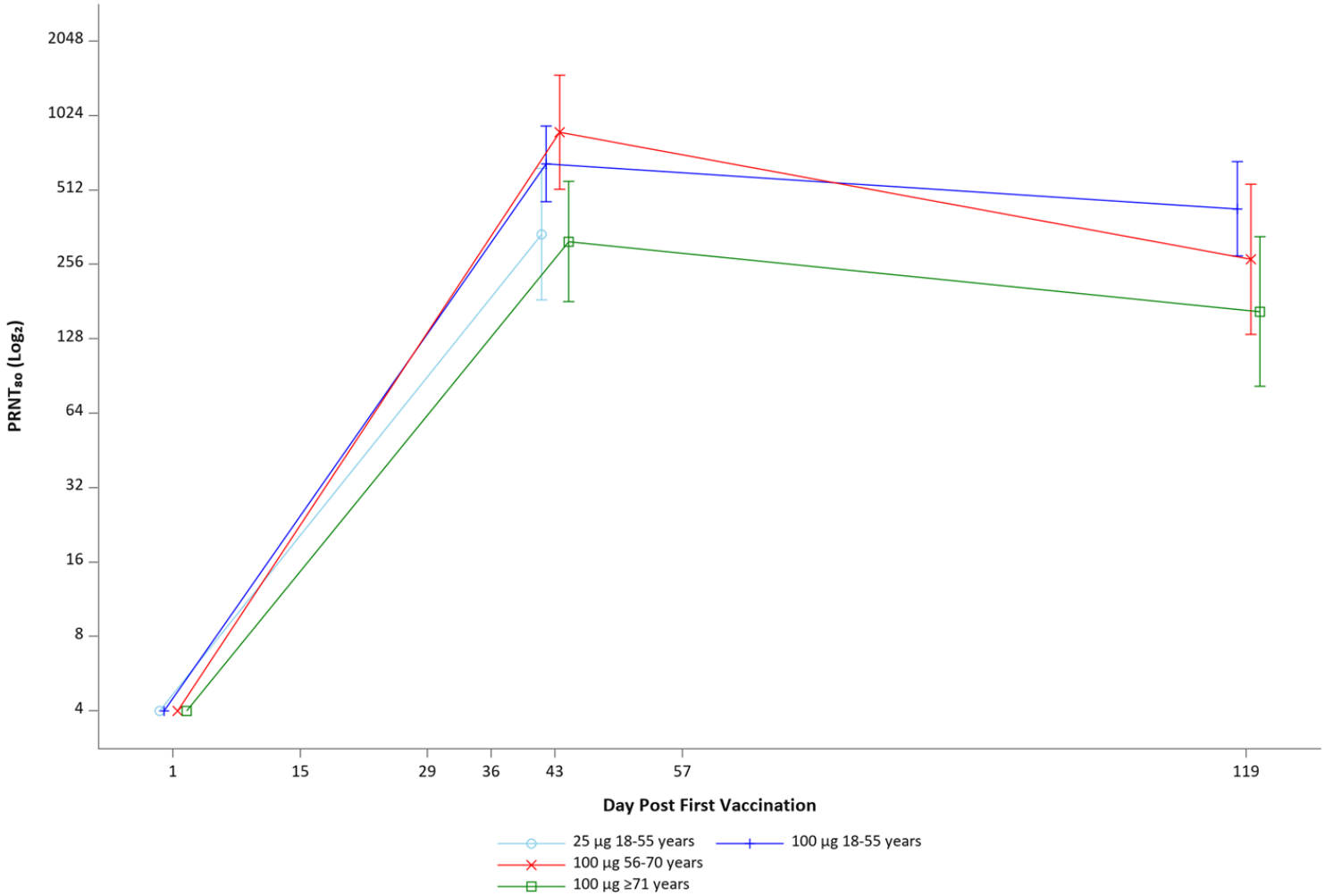
Figure 20: PRNT Geometric Mean by Time Point and Vaccination Group – $PRNT_{80}$



Abbreviation: PRNT = plaque reduction neutralization test; $PRNT_{80}$ = highest serum dilution reducing virus infectivity by 80% as measured by plaque reduction neutralization test

Source: Posttext Figure 20.

10.4 SARS-CoV-2 Live-Virus Focus-Reduction Neutralization Test Using mNeon Green (FRNT-mNG)

Serum neutralizing activity was assessed using a high-throughput live-virus reporter assay, the FRNT-mNG. The FRNT-mNG GM neutralizing ID_{50} (Figure 21) and ID_{80} (Figure 22) titers were undetectable prior to the first injection, marginally increased after the first injection, and substantially increases after the second injection on Day 43 for all age groups and mRNA-1273 dose groups. The FRNT-mNG GM titers persisted through Day 119 with a modest decline from Day 43 levels but exceeded the neutralizing titers for the convalescent sera control group (Posttext Table 39, Posttext Table 40, and Posttext Table 41 for ID_{50} and Posttext Table 42, Posttext Table 43, and Posttext Table 44 for ID_{80}).

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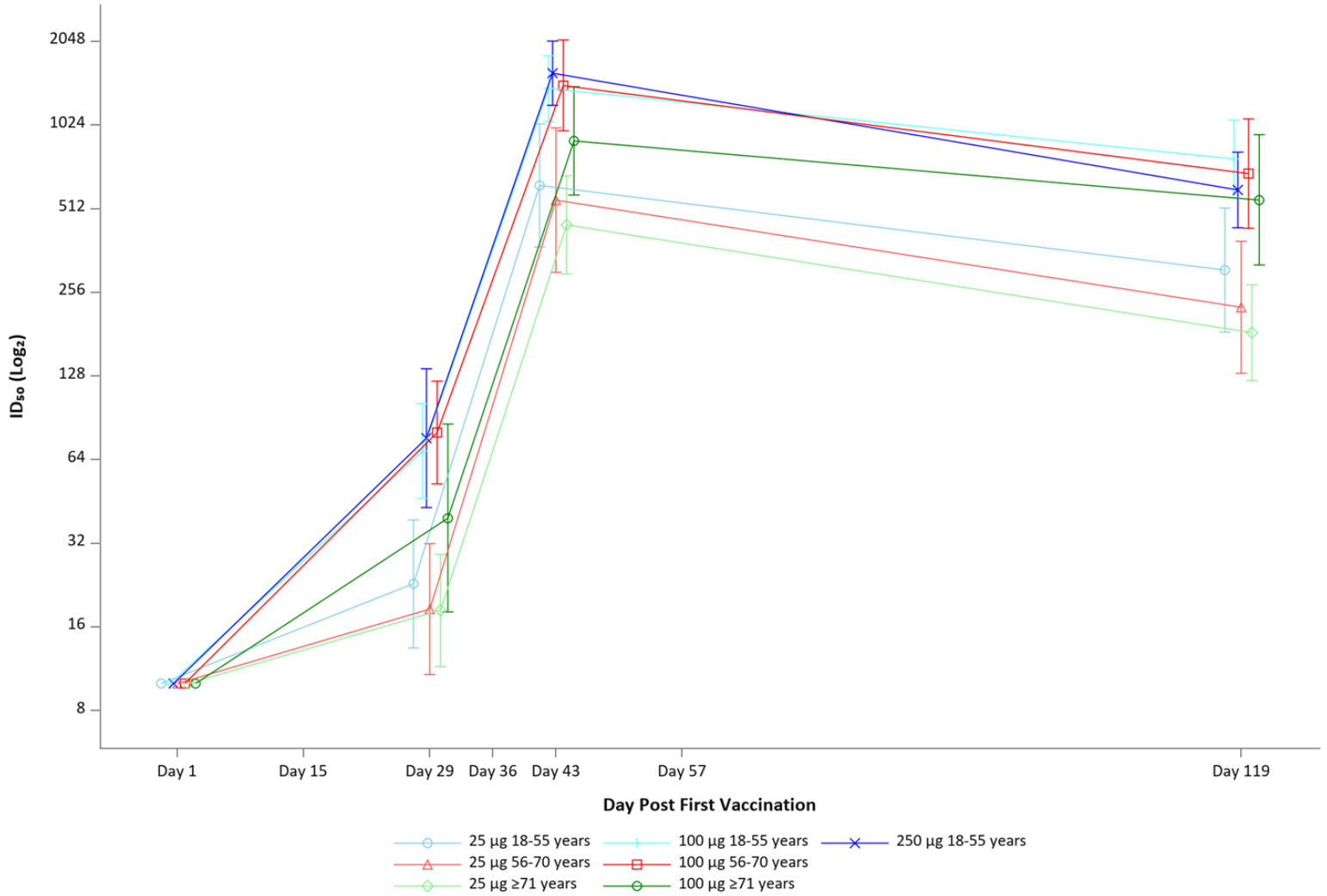
Figure 21: FRNT-mNG Geometric Mean by Time Point and Vaccination Group – ID_{50}



Abbreviations: FRNT-mNG = focus-reduction neutralization test using mNeonGreen; ID_{50} = serum dilution required to achieve 50% neutralization
Source: Posttext Figure 22.

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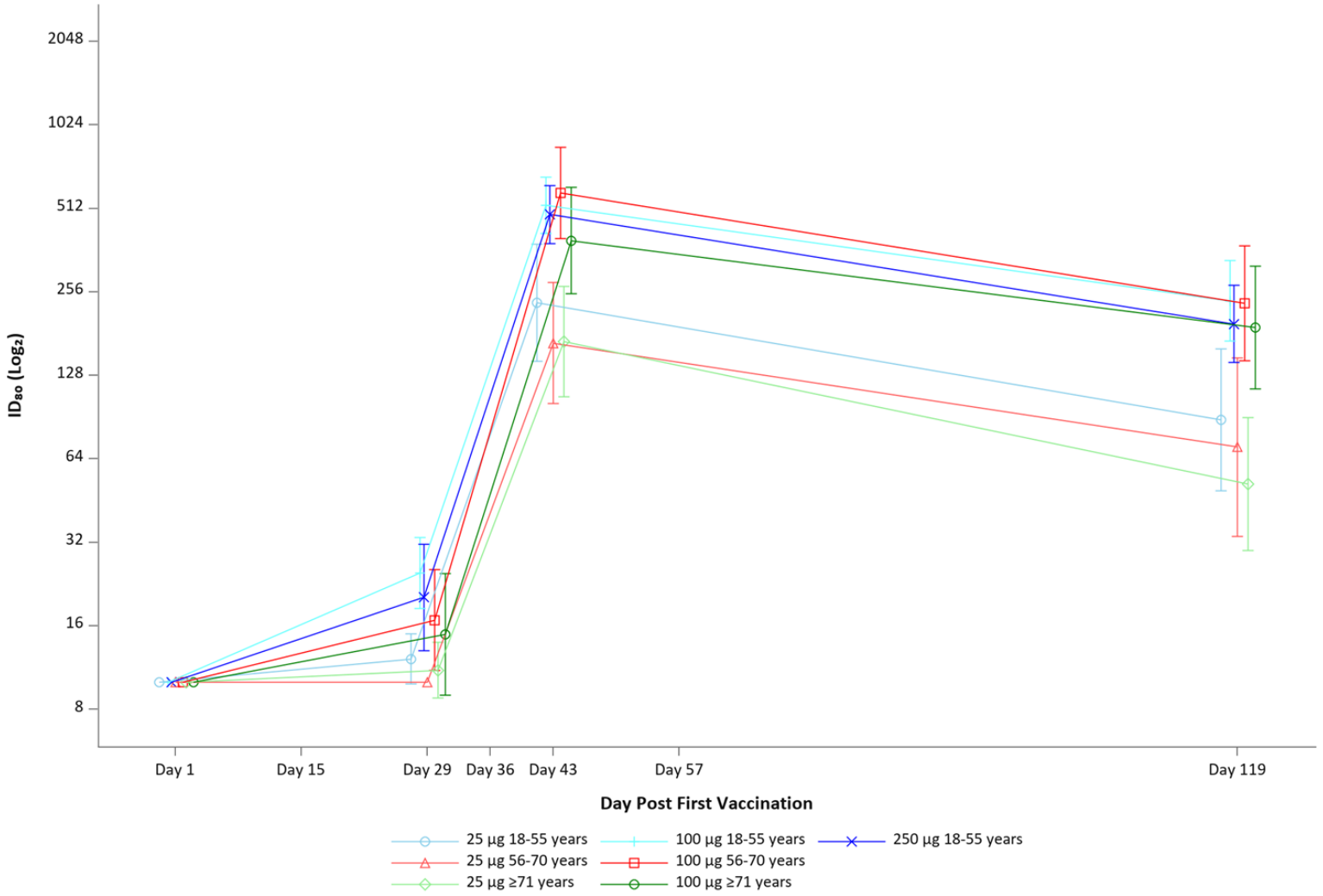
Figure 22: FRNT-mNG Geometric Mean by Time Point and Vaccination Group – ID_{80}



Abbreviations: FRNT-mNG = focus-reduction neutralization test using mNeonGreen; ID_{80} = serum dilution required to achieve 80% neutralization
Source: Posttext Figure 23.

10.5 Humoral Immunogenicity Intra- and Interassay Correlations

A heatmap explaining correlations within and between the values from binding antibody assays (full-length S-2P and RBD) and neutralizing activity as assessed by PsVNA, PRNT, and FRNT-mNG is provided in Figure 23.

The correlations found within and between the values from binding antibody assays and neutralizing activity were as follows:

- Binding antibody responses to S-2P proteins in ELISA expressed as AUC and endpoint dilution titers. This was also confirmed for the convalescent sera panel (Posttext Figure 54).
- Binding antibody responses to S-2P and RBD. This was also confirmed for the convalescent sera samples (Posttext Figure 55).
- PsVNA (ID_{50} and ID_{80}) and S-2P binding (Posttext Figure 56).
- $PRNT_{80}$ and S-2P binding (Posttext Figure 57).
- $PRNT_{80}$ and RBD binding (Posttext Figure 57).
- FRNT-mNG (ID_{50}) and S-2P binding (Posttext Figure 58).
- FRNT-mNG (ID_{50}) and RBD binding (Posttext Figure 58).

The correlation analysis results provides orthogonal support for each assay in characterizing the humoral response induced by mRNA-1273.

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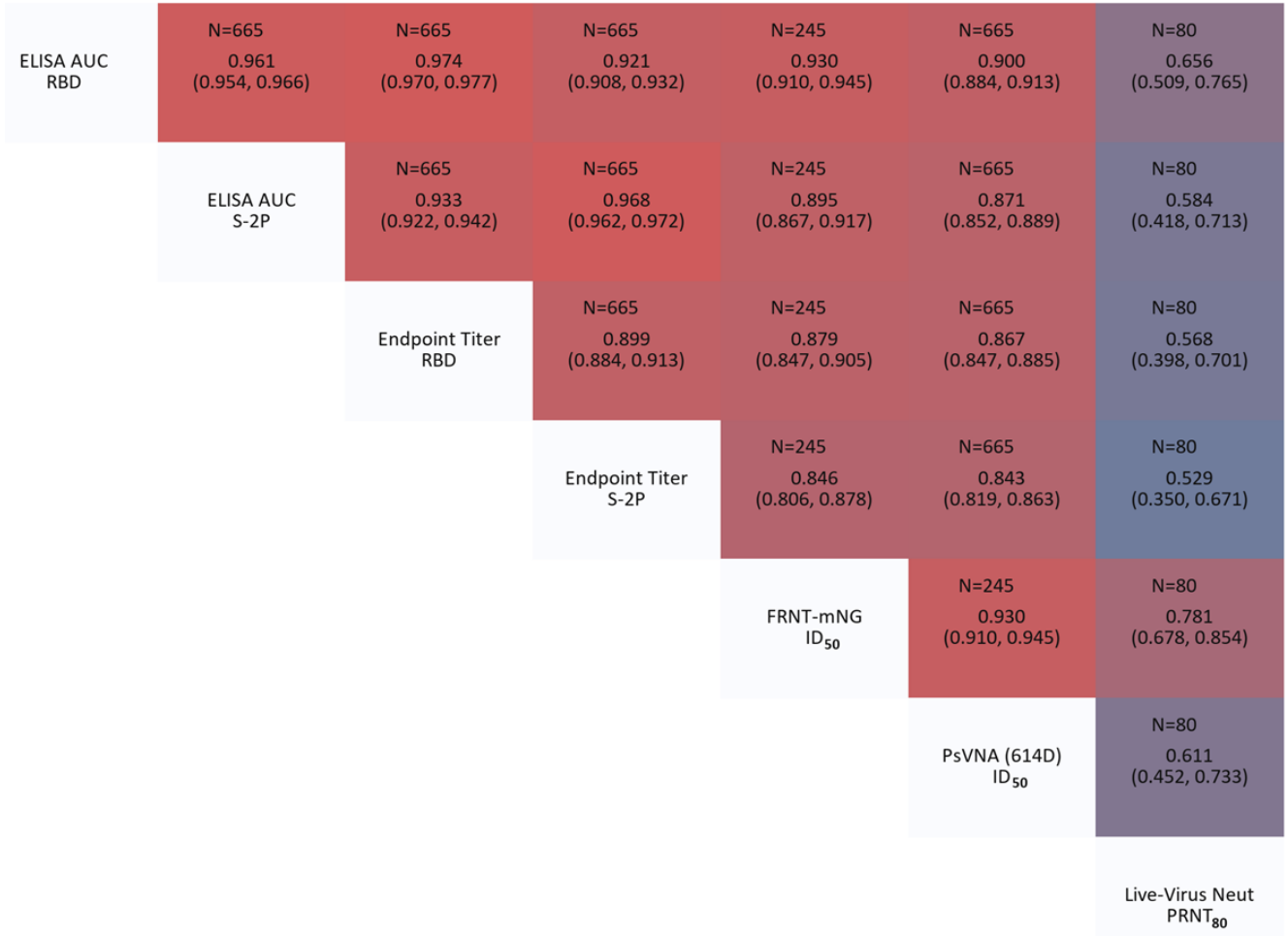
Figure 23: Correlation Heatmap



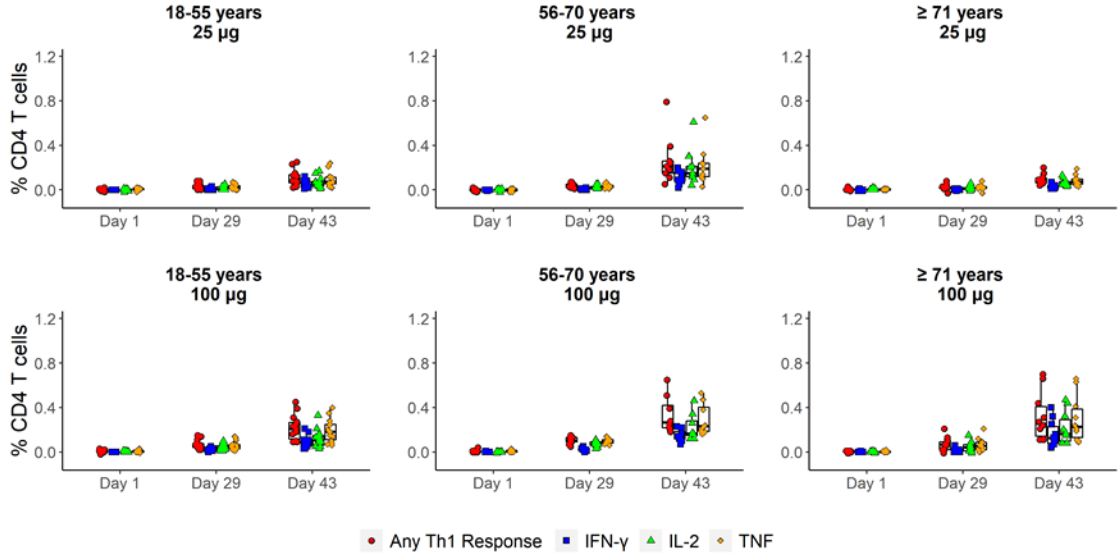
Abbreviations: AUC = area under the curve; ELISA = enzyme-linked immunosorbent assay; FRNT-mNG = focus-reduction neutralization test using mNeonGreen; ID_{50} = serum dilution required to achieve 50% neutralization; Neut = neutralization; $PRNT_{80}$ = highest serum dilution reducing virus infectivity by 80% as measured by plaque reduction neutralization test; PsVNA = psuedovirus neutralization assay; RBD = receptor binding domain; S-2P = spike protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein into a prefusion conformation.

Source: Posttext Figure 59.

10.6 SARS-CoV-2 S Protein-Specific T-Cell Responses

mRNA-1273 at the 25 and 100 µg doses elicited CD4 T-cell responses that, upon stimulation by S-specific peptide pools, were strongly biased towards the expression of Th1 cytokines (tumor necrosis factor α > interleukin 2 > interferon γ [Figure 24 and Figure 26]) with minimal T-helper 2 (Th2) cytokine expression (interleukin 4 and interleukin 13 [Figure 25 and Figure 27]). The responses to the 100 µg dose were numerically higher than those for the 25 µg dose across all age groups. The CD8 T-cell responses were low to absent across the age stratum in the 25 µg and 100 µg vaccination groups (Figure 28 and Figure 29).

Figure 24: Percentages of CD4 T Cells Expressing Th1 Cytokines – S1 Peptide Pool



Abbreviations: IFN-γ = interferon γ; IL-2 = interleukin 2; Th1 = T-helper 1; TNF = tumor necrosis factor
Source: Posttext Figure 60.

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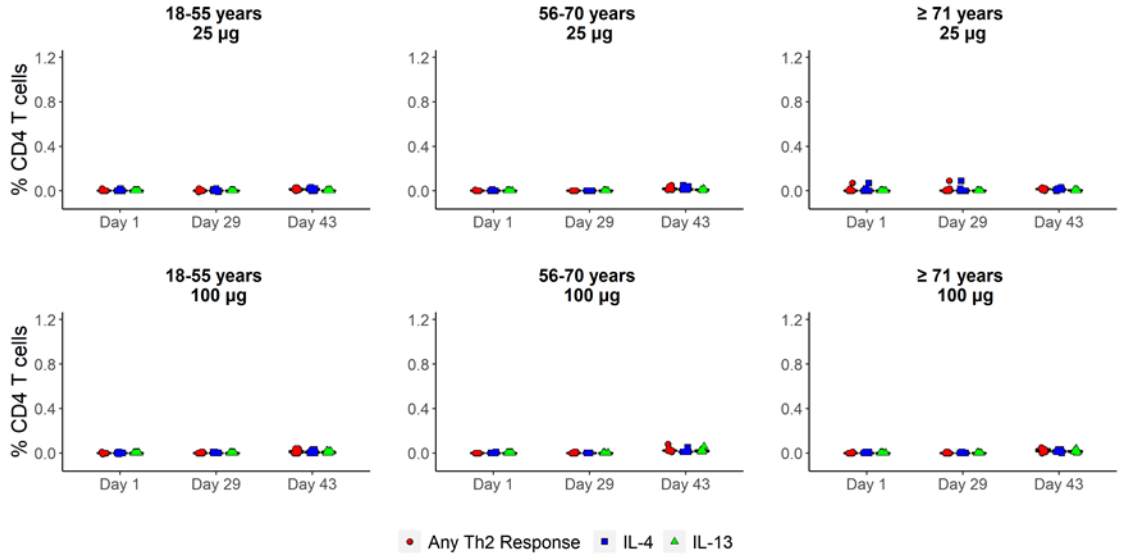
Figure 25: Percentages of CD4 T Cells Expressing Th2 Cytokines – S1 Peptide Pool



Abbreviations: IL-4 = interleukin 4; IL-13 = interleukin 13; Th2 = T-helper 2
Source: Posttext Figure 61.

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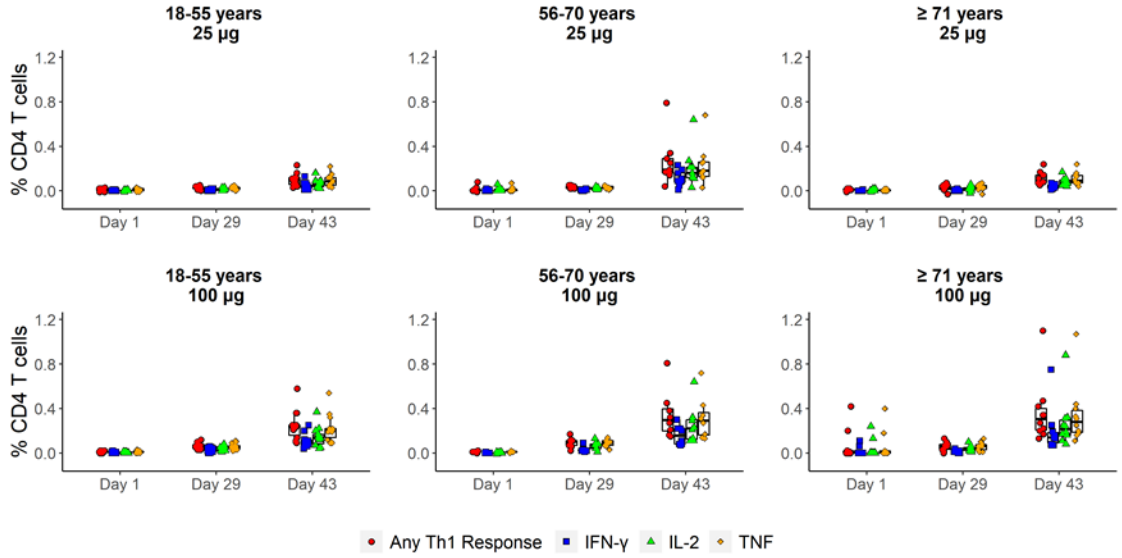
Figure 26: Percentages of CD4 T Cells Expressing Th1 Cytokines – S2 Peptide Pool



Abbreviations: IFN-γ = interferon γ; IL-2 = interleukin 2; Th1 = T-helper 1; TNF = tumor necrosis factor
Source: Posttext Figure 62.

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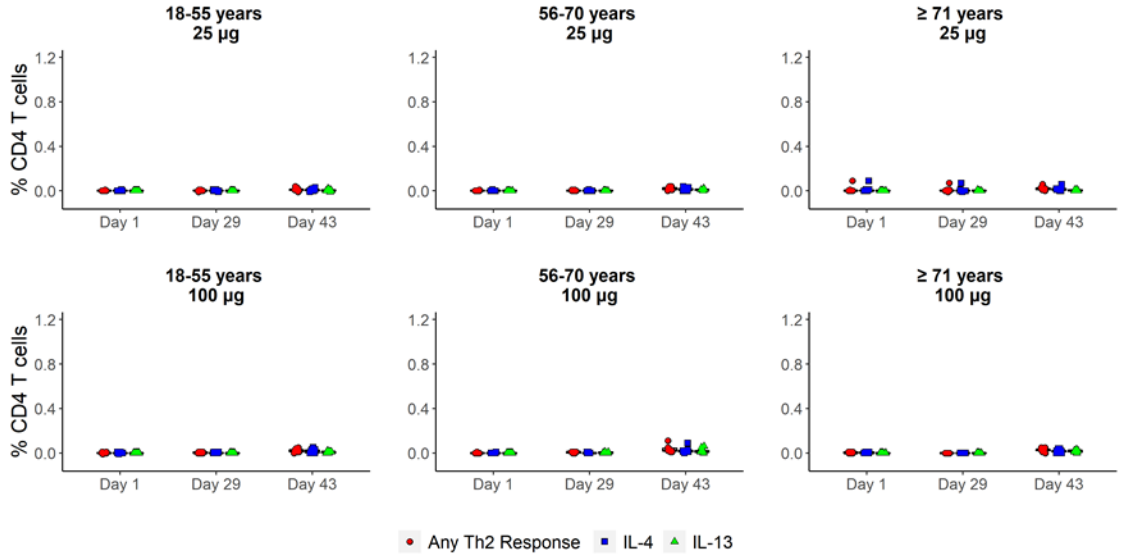
Figure 27: Percentages of CD4 T Cells Expressing Th2 Cytokines – S2 Peptide Pool



Abbreviations: IL-4 = interleukin 4; IL-13 = interleukin 13; Th2 = T-helper 2
Source: Posttext Figure 63

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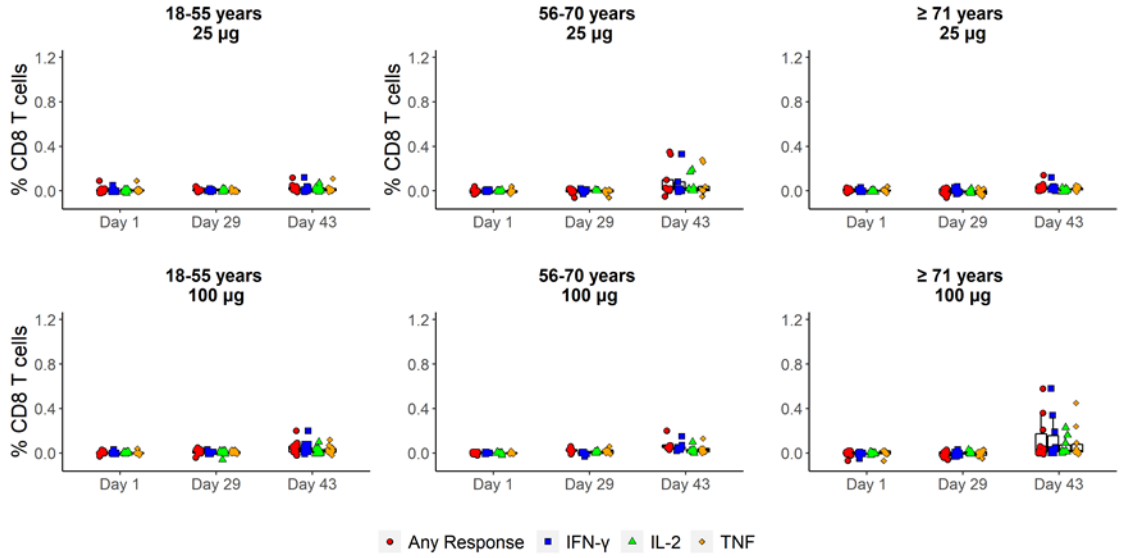
Figure 28: Percentages of CD8 T Cells Expressing Cytokines – S1 Peptide Pool



Abbreviation: IFN-γ = interferon γ; IL-2 = interleukin 2; TNF = tumor necrosis factor
Source: Posttext Figure 64.

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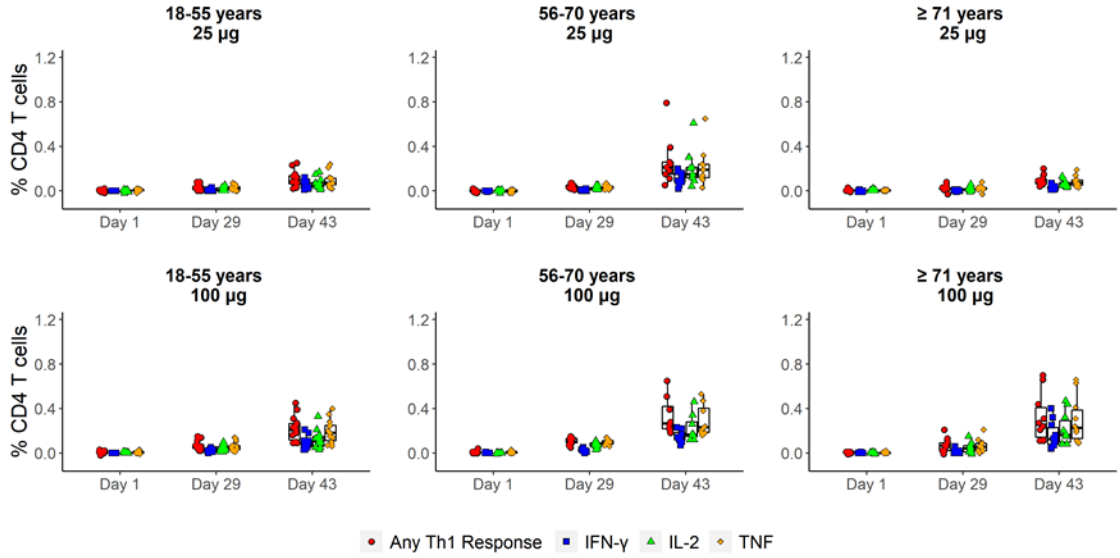
Figure 29: Percentages of CD8 T Cells Expressing Cytokines – S2 Peptide Pool



Abbreviation: IFN-γ = interferon γ; IL-2 = interleukin 2; TNF = tumor necrosis factor
Source: Posttext Figure 65.

10.7 Immunogenicity Conclusions

mRNA-1273 administered as 2 doses separated by 28 days induced robust humoral and cellular immune responses. In general, dose-dependent increases in binding and neutralizing antibody responses were detected across age groups. Binding and neutralizing antibody responses among all age groups for the 100 µg vaccination dose persisted through Day 119 at levels that declined modestly relative to Day 57 but remained similar to or higher than responses in a convalescent sera panel. mRNA-1273 elicited a strong Th1-biased CD4 T cell response.

- S-2P IgG ELISA Endpoint
    - The S-2P ELISA results demonstrated a robust antibody response after each dose. The S-2P ELISA GMT values were generally numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups across all age groups. The S-2P ELISA GMT values in the 250 µg vaccination group were numerically higher than those in the 100 µg vaccination group in the 18 to 55 years of age group.

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- The S-2P ELISA GMT values for Day 43 and Day 57 were numerically higher than those for the convalescent sera control group across all age groups and dosage levels.

- Seroconversion (4-fold rise in endpoint titer from baseline) to S-2P was observed by Day 15 in all participants in the 18-55 years of age groups, by Day 29 in all participants in the 56-70 years of age groups, and by Day 36 in all participants in the ≥71 years of age group.

- For the 100 µg and 250 µg mRNA-1273 doses, the S-2P ELISA GMT values at Day 119 were numerically higher than that for the convalescent sera control group.

- RBD IgG ELISA Endpoint

  - The RBD ELISA results demonstrated a robust antibody response after each dose.

  - The RBD ELISA GMT values were numerically higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups in the 56 to 70 and ≥ 71 years of age groups.

  - For all age groups and mRNA-1273 dose levels, the RBD ELISA GMT values for Day 36 and beyond exceeded the median GMT values for the convalescent sera control group.

  - The RBD ELISA GMFR results consistently showed robust responses across all age groups, and the seroconversion criteria were met at the majority of postbaseline visits.

- Pseudovirus Neutralization ID_{50} and ID_{80}

  - The PsVNA GM titers (ID_{50} and ID_{80}) for the 614D variant were undetectable prior to the first injection, marginally increased after the first injection, and substantially increased after the second injection.

  - The PsVNA GM titers (ID_{50} and ID_{80}) after 2 injections were similar at Day 57 among the 50 µg, 100 µg, and 250 µg vaccination groups in the 18 to 55 years of age group. In both the 56 to 70 and ≥ 71 years of age groups, the PsVNA GM

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titers (ID_{50} and ID_{80}) after 2 injections numerically were higher in the 100 µg vaccination group than in the 25 µg and 50 µg vaccination groups.

  - The GM titers for the 100 µg mRNA-1273 vaccination group from Day 36 through Day 119 were similar to (≥ 71 years of age group) or exceeded (18 to 55 and 56 to 70 years of age groups) the GM titers from the convalescent sera control group.

  - Robust neutralizing antibody responses to the 614G variant were also observed at Day 43 for the 100 µg vaccination group regardless of age.

- $PRNT_{80}$ GMT

  - The $PRNT_{80}$ GM values were undetectable prior to the first injection but were readily detectable and increased substantially after the second injection.

- FRNT-mNG

  - The FRNT-mNG GM neutralizing titers (ID_{50} and ID_{80}) were undetectable prior to the first injection, marginally increased after the first injection, and substantially increased after the second injection on Day 43 for all age groups and mRNA-1273 dose groups.

- Correlations were found within and between the values from binding antibody assays and neutralizing activity. The correlation between live-virus and pseudovirus neutralization with S-2P and RBD ELISA provides orthogonal support for each assay in characterizing the humoral response induced by mRNA-1273.

The T-cell response data supported the cellular immunity profile for mRNA-1273 with the following observations:

- The 25 and 100 µg doses elicited CD4 T-cell responses that, upon stimulation by S-specific peptide pools, were strongly biased toward the expression of Th1 cytokines (tumor necrosis factor α > interleukin 2 > interferon γ) with minimal Th2 cytokine expression (interleukin 4 and interleukin 13). The responses to the 100 µg dose were numerically higher than those for the 25 µg dose across all age groups.

- The CD8 T-cell responses were low to absent across the age stratum in the 25 µg and 100 µg vaccination groups.

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11 Biomarker Results

Not applicable.

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12 Conclusions

Safety

mRNA-1273, administered as 2 doses 28 days apart, was safe and immunogenic in healthy adult participants aged ≥ 18 years. After mRNA-1273 administration, fatigue, headache, myalgia, feverishness, and injection site pain were the most commonly reported solicited systemic and local ARs, with higher incidence noted after the second injection than after the first injection for the solicited systemic ARs. Most of the solicited ARs were mild or moderate; severe solicited ARs predominantly occurred at the highest dose (250 µg). The ARs lasted a median of 2 days or less. In general, ARs were less severe and less commonly reported in older than in younger adults. All unsolicited AEs related to mRNA-1273 were mild or moderate in severity, except for 2 severe AEs reported in 1 participant in the 250 µg vaccination group (18 to 55 years of age group).

Immunogenicity

mRNA-1273 induced robust binding antibody responses (S-2P and RBD specific) after 2 injections. Notably, 100 µg of mRNA-1273 resulted in numerically higher S-2P specific binding titers than 25 µg and 50 µg of mRNA-1273 in all age groups and higher RBD–specific binding titers in participants aged > 55 years. Two injections of mRNA-1273 induced robust neutralizing antibody responses. The neutralizing antibody response increased marginally after the first injection but increased substantially after the second injection. The neutralizing antibody response (assessed by a pseudovirus neutralization assay) at the 100 µg mRNA-1273 dose level was similar to that at the 250 µg mRNA-1273 dose level in the 18 to 55 years of age group and numerically higher than that observed at the 25 µg and 50 µg mRNA-1273 dose levels in the older age groups. The neutralizing antibody response at the 100 µg dose was similar across all age groups. mRNA-1273 also elicited CD4 T-cell responses that, upon stimulation by S-specific peptide pools, were strongly biased toward the expression of Th1 cytokines.

Based on the results of safety and immunogenicity at data cutoff, the 100 µg dose provides promising immunogenicity results in adults of all ages with an acceptable safety profile and was the dose selected for further evaluation in the Phase 3 clinical study.

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Figure 114 Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Nausea
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14.3.2 Displays of Deaths and Other Serious and Clinically Meaningful Adverse Events

Number	Title
Table 126	Listing of Serious Adverse Events
Table 127	Listing of MAAEs and NOCMCs

14.3.3 Displays of Laboratory Values

Number	Title
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Table 129	Laboratory Results by Parameter, Severity, and Study Day Serum Creatinine
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Table 154 Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Hemoglobin
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Figure 123 Clinical Laboratory Results by Severity and Treatment Group 18-55 Years of Age
Figure 124 Clinical Laboratory Results by Severity and Treatment Group 56-70 Years of Age
Figure 125 Clinical Laboratory Results by Severity and Treatment Group ≥71 years of Age

14.3.4 Data Listings (Each Participant) for Abnormal Clinically Meaningful Laboratory Values, Vital Signs, Physical Examinations, and Other Observations Related to Safety

Individual participant data listings are presented in Appendix 16.2.

14.4 Additional Safety Data

Number	Title
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Table 158	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age
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Table 160	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age
Table 161	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age
Table 162	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age
Table 163	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age
Table 164	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age
Table 165	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age
Table 166	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age
Table 167	Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

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Table 168 Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age
Table 169 Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age
Table 170 Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age
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TABLE 1:
Subject Disposition by Treatment Group - 18-55 Years of Age

	25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screened	.	.	.	.	.	.	.	.	.	.
Enrolled	15	100	15	100	15	100	15	100	60	100
Received the first vaccination	15	100	15	100	15	100	15	100	60	100
Discontinued treatment[a]	2	13	.	.	.	.	1	7	3	5
Received the second vaccination	13	87	15	100	15	100	14	93	57	95
Discontinued treatment[a]	2	13	.	.	.	.	1	7	3	5
Study ongoing	15	100	15	100	15	100	15	100	60	100
Early termination[a]	.	.	.	.	.	.	.	.	.	.
Completed study	.	.	.	.	.	.	.	.	.	.

[a]Refer to Listing 2 for reasons subjects discontinued or terminated early.

TABLE 2:
Subject Disposition by Treatment Group - 56-70 Years of Age

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screened	.	.	.	.	.	.	.	.
Enrolled	10	100	10	100	10	100	30	100
Received the first vaccination	10	100	10	100	10	100	30	100
Discontinued treatment[a]	.	.	.	.	1	10	1	3
Received the second vaccination	10	100	10	100	9	90	29	97
Discontinued treatment[a]	.	.	.	.	1	10	1	3
Study ongoing	10	100	10	100	10	100	30	100
Early termination[a]	.	.	.	.	.	.	.	.
Completed study	.	.	.	.	.	.	.	.

[a]Refer to Listing 2 for reasons subjects discontinued or terminated early.

TABLE 3:
Subject Disposition by Vaccination Group - ≥71 years of Age

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screened	.	.	.	.	.	.	.	.
Enrolled	10	100	10	100	10	100	30	100
Received the first vaccination	10	100	10	100	10	100	30	100
Discontinued treatment[a]	.	.	.	.	.	.	.	.
Received the second vaccination	10	100	10	100	10	100	30	100
Discontinued treatment[a]	.	.	.	.	.	.	.	.
Study ongoing	10	100	10	100	10	100	30	100
Early termination[a]	.	.	.	.	.	.	.	.
Completed study	.	.	.	.	.	.	.	.

[a]Refer to Listing 2 for reasons subjects discontinued or terminated early.

Table 4: Analysis Populations by Treatment Group

Analysis Populations	Treatment Group	Reason Subjects Excluded	n	%
Per Protocol	25 µg (18-55 years)	Any Reason	2	13
		Did not Receive Second Dose	2	13
	50 µg (18-55 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	100 µg (18-55 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	250 µg (18-55 years)	Any Reason	1	7
		Did not Receive Second Dose	1	7
	25 µg (56-70 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	50 µg (56-70 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	100 µg (56-70 years)	Any Reason	1	7
		Did not Receive Second Dose	1	7
	25 µg (≥71 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	50 µg (≥71 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
	100 µg (≥71 years)	Any Reason	-	-
		Did not Receive Second Dose	-	-
Note: Visits post Day 29 were removed for subjects that did not receive a second dose.				

Table 5: Ineligibility Summary of Screen Failures

Inclusion/Exclusion	Inclusion/Exclusion Criteria	# of Times Item Marked Ineligible
EXCLUSION	Has participated in another investigational study involving any investigational product.	1
	Has a positive test for hep B, hep C or HIV antibodies at screening.	2
	Has any abnormality or body art that would interfere with the ability to observe local reactions.	1
	Has a positive test result for drugs of abuse at screening or before first vaccination.	1
	Chronic use of any medications that may be associated with impaired immune responsiveness	1
	Current use of any medications within 7 days prior to vaccination.	2
	Has any medical disease or condition that precludes study participation.	6
	Receipt of any other SARS-CoV-2 or other experimental coronavirus vaccine at any time.	2
	Presence of self-reported or medically documented medical or psychiatric condition	8
INCLUSION	Body Mass Index 18-35 kg/m2 inclusive, at screening.	2
	In good health	1
	BMI: 18-35 kg/m2 inclusive for < 56 years of age; 18-30 kg/m2 inclusive for >= 56 years of age	6
	Screening laboratory evaluations are within acceptable normal ranges	56
	Be able to understand and agrees to comply with study procedures and be available for study visits.	4
	Systolic blood pressure is within the protocol eligibility criteria.	11
	Time commitment	1

ELIGIBLE BUT NOT ENROLLED	Not enrolled other reason: participant numbers already met	1
	Not enrolled other reason: enrollment target reached	1
	Not enrolled other reason: enrollment closed	2
	Not enrolled other reason: Enrollment target reached	4
	Not enrolled other reason: Enrollment numbers met	3
	Not enrolled other reason: Enrollment goal met	1
	Not enrolled other reason: Enrollment full	10
	Not enrolled other reason: Cohort closed to accrual	7
	Not enrolled other reason: Backup, cohort limit met	3
	Concern of potential risk	5

TABLE 6:
Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - All Subjects 18-55 Years of Age

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Demographic Category	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Sex	Male	9	60	9	60	7	47	6	40	31	52
	Female	6	40	6	40	8	53	9	60	29	48
Ethnicity	Not Hispanic or Latino	14	93	14	93	12	80	12	80	52	87
	Hispanic or Latino	1	7	1	7	3	20	2	13	7	12
	Not Reported	.	.	.	.	.	.	1	7	1	2
	Unknown	.	.	.	.	.	.	.	.	.	.
Race	American Indian or Alaska Native	.	.	.	.	1	7	.	.	1	2
	Asian	.	.	2	13	.	.	1	7	3	5
	Native Hawaiian or other Pacific Islander	.	.	.	.	.	.	.	.	.	.
	Black	.	.	.	.	2	13	.	.	2	3
	White	15	100	13	87	11	73	14	93	53	88
	Multi Racial	.	.	.	.	.	.	.	.	.	.
	Unknown	.	.	.	.	1	7	.	.	1	2

TABLE 7:
Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - All Subjects 56-70 Years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Demographic Category	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Sex	Male	3	30	5	50	5	50	13	43
	Female	7	70	5	50	5	50	17	57
Ethnicity	Not Hispanic or Latino	10	100	10	100	10	100	30	100
	Hispanic or Latino	.	.	.	.	.	.	.	.
	Not Reported	.	.	.	.	.	.	.	.
	Unknown	.	.	.	.	.	.	.	.
Race	American Indian or Alaska Native	.	.	.	.	.	.	.	.
	Asian	.	.	1	10	.	.	1	3
	Native Hawaiian or other Pacific Islander	.	.	.	.	.	.	.	.
	Black	.	.	1	10	.	.	1	3
	White	10	100	7	70	10	100	27	90
	Multi Racial	.	.	1	10	.	.	1	3
	Unknown	.	.	.	.	.	.	.	.

TABLE 8:
Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - All Subjects ≥71 years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Demographic Category	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Sex	Male	8	80	6	60	3	30	17	57
	Female	2	20	4	40	7	70	13	43
Ethnicity	Not Hispanic or Latino	9	90	9	90	10	100	28	93
	Hispanic or Latino	1	10	1	10	.	.	2	7
	Not Reported	.	.	.	.	.	.	.	.
	Unknown	.	.	.	.	.	.	.	.
Race	American Indian or Alaska Native	.	.	.	.	.	.	.	.
	Asian	1	10	.	.	.	.	1	3
	Native Hawaiian or other Pacific Islander	.	.	.	.	.	.	.	.
	Black	.	.	.	.	.	.	.	.
	White	9	90	10	100	10	100	29	97
	Multi Racial	.	.	.	.	.	.	.	.
	Unknown	.	.	.	.	.	.	.	.

TABLE 9:
Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - All Subjects 18-55 Years of Age

		25 µg mRNA-1273 (N=15)	50 µg mRNA -1273 (N=15)	100 µg mRNA -1273 (N=15)	250 µg mRNA -1273 (N=15)	All Subjects (N=60)
Variable	**Statistic**					
Age (Years)	Mean	36.7	37.0	31.3	31.0	34.0
	Standard Deviation	7.9	10.0	8.7	8.0	8.9
	Median	35.9	34.6	31.6	30.3	32.1
	Minimum	25	22	20	18	18
	Maximum	53	54	53	50	54
Height (cm)	Mean	175.70	176.39	171.33	167.93	172.84
	Standard Deviation	9.18	8.73	7.32	11.25	9.64
	Median	174.50	178.60	170.00	165.10	172.70
	Minimum	158.7	162.6	160.7	152.7	152.7
	Maximum	194.1	188.8	188.0	185.7	194.1
Weight (kg)	Mean	76.44	72.55	78.67	70.10	74.44
	Standard Deviation	14.86	15.05	10.69	13.70	13.75
	Median	72.20	73.00	78.50	74.10	73.90
	Minimum	56.2	50.9	54.2	52.1	50.9
	Maximum	107.9	108.0	98.7	95.9	108.0
BMI (kg/m^2)	Mean	24.62	23.12	26.73	24.68	24.79
	Standard Deviation	3.45	3.16	2.60	3.09	3.28
	Median	24.50	22.60	27.40	23.70	24.45
	Minimum	21.1	18.5	20.4	20.4	18.5
	Maximum	32.6	30.3	31.5	29.4	32.6

TABLE 10:
Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - All Subjects 56-70 Years of Age

		25 µg mRNA-1273 (N=10)	50 µg mRNA-1273 (N=10)	100 µg mRNA-1273 (N=10)	All Subjects (N=30)
Variable	**Statistic**				
Age (Years)	Mean	65.8	62.1	63.8	63.9
	Standard Deviation	4.5	3.7	4.3	4.3
	Median	67.0	61.6	64.5	65.0
	Minimum	56	56	56	56
	Maximum	70	68	69	70
Height (cm)	Mean	169.64	173.62	170.19	171.15
	Standard Deviation	11.59	9.36	11.43	10.62
	Median	167.60	177.00	169.35	170.60
	Minimum	149.0	157.5	152.4	149.0
	Maximum	186.0	186.7	195.6	195.6
Weight (kg)	Mean	73.47	71.05	69.40	71.31
	Standard Deviation	12.77	11.75	13.62	12.40
	Median	70.45	71.90	65.60	69.45
	Minimum	52.0	52.0	50.5	50.5
	Maximum	89.8	87.0	95.2	95.2
BMI (kg/m^2)	Mean	25.38	23.41	23.73	24.17
	Standard Deviation	2.53	2.02	2.26	2.37
	Median	24.85	23.25	23.80	23.45
	Minimum	22.4	21.0	20.8	20.8
	Maximum	29.5	27.8	27.4	29.5

TABLE 11:
Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - All Subjects ≥71 years of Age

		25 µg mRNA-1273 (N=10)	50 µg mRNA-1273 (N=10)	100 µg mRNA-1273 (N=10)	All Subjects (N=30)
Variable	**Statistic**				
Age (Years)	Mean	72.8	75.1	72.6	73.5
	Standard Deviation	1.2	3.4	1.1	2.4
	Median	72.6	73.6	72.6	72.9
	Minimum	71	72	71	71
	Maximum	75	83	75	83
Height (cm)	Mean	171.03	171.97	166.57	169.86
	Standard Deviation	8.21	9.51	8.43	8.76
	Median	172.45	170.00	167.25	170.30
	Minimum	153.9	161.0	152.5	152.5
	Maximum	180.1	188.0	181.7	188.0
Weight (kg)	Mean	72.95	72.86	72.16	72.66
	Standard Deviation	13.81	9.37	10.89	11.11
	Median	78.30	73.05	69.80	74.45
	Minimum	47.4	56.3	57.9	47.4
	Maximum	87.6	86.2	91.2	91.2
BMI (kg/m^2)	Mean	24.76	24.66	26.02	25.15
	Standard Deviation	3.53	2.72	3.52	3.22
	Median	25.80	24.60	26.70	25.35
	Minimum	19.9	20.7	20.1	19.9
	Maximum	29.2	29.1	29.7	29.7

TABLE 12:
Distribution of Protocol Deviations by Category, Type, and Treatment Group - 18-55 Years of Age

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Category	**Deviation Type**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**
Follow-up visit schedule	**Missed visit/visit not conducted**	-	-	-	-	-	-	-	-	-	-
	Out of window visit	-	-	2	2	1	2	-	-	3	4
Protocol procedure/assessment	**Other: breach of confidentiality**	-	-	-	-	1	1	-	-	1	1
	Other: non-required lab tests performed	1	1	-	-	-	-	-	-	1	1
	Other: v4 safety labs collected out of window	1	1	-	-	-	-	-	-	1	1
	Required procedure done incorrectly	1	1	2	2	2	3	2	2	7	8
	Required procedure not conducted	1	1	-	-	-	-	1	1	2	2
	Specimen result not obtained	-	-	-	-	-	-	-	-	-	-
	Too few aliquots obtained	-	-	-	-	6	9	2	5	8	14
Treatment administration schedule	**Required procedure done incorrectly**	-	-	-	-	-	-	1	1	1	1

TABLE 13:
Distribution of Protocol Deviations by Category, Type, and Treatment Group - 56-70 Years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA -1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Category	**Deviation Type**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**
Follow-up visit schedule	**Missed visit/visit not conducted**	-	-	-	-	1	1	1	1
	Out of window visit	1	1	-	-	-	-	1	1
Protocol procedure/assessment	**Other: breach of confidentiality**	-	-	-	-	-	-	-	-
	Other: non-required lab tests performed	-	-	-	-	-	-	-	-
	Other: v4 safety labs collected out of window	-	-	-	-	-	-	-	-
	Required procedure done incorrectly	-	-	-	-	-	-	-	-
	Required procedure not conducted	-	-	-	-	-	-	-	-
	Specimen result not obtained	-	-	-	-	-	-	-	-
	Too few aliquots obtained	2	2	-	-	-	-	2	2
Treatment administration schedule	**Required procedure done incorrectly**	-	-	-	-	-	-	-	-

TABLE 14:
Distribution of Protocol Deviations by Category, Type, and Treatment Group - ≥71 years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA -1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Category	**Deviation Type**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**	**#of Subj.**	**#of Dev.**
Follow-up visit schedule	**Missed visit/visit not conducted**	-	-	-	-	-	-	-	-
	Out of window visit	-	-	-	-	-	-	-	-
Protocol procedure/assessment	**Other: breach of confidentiality**	-	-	-	-	-	-	-	-
	Other: non-required lab tests performed	-	-	-	-	-	-	-	-
	Other: v4 safety labs collected out of window	-	-	-	-	-	-	-	-
	Required procedure done incorrectly	-	-	-	-	-	-	-	-
	Required procedure not conducted	-	-	-	-	-	-	-	-
	Specimen result not obtained	-	-	-	-	1	1	1	1
	Too few aliquots obtained	1	1	-	-	2	2	3	3
Treatment administration schedule	**Required procedure done incorrectly**	-	-	-	-	-	-	-	-

Table 172: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group All Subjects 18-55 Years of Age

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Level 1 Codes	**Any Level 2 Codes**	14	93	15	100	15	100	14	93	58	97
Alimentary Tract And Metabolism	**Any Level 2 Codes**	10	67	11	73	8	53	10	67	39	65
	Antidiarrheals, Intestinal Antiinflammatory /Antiinfective Agents	-	-	-	-	2	13	1	7	3	5
	Antiemetics And Antinauseants	2	13	1	7	1	7	1	7	5	8
	Digestives, Incl. Enzymes	-	-	-	-	1	7	-	-	1	2
	Drugs For Acid Related Disorders	3	20	1	7	-	-	5	33	9	15
	Drugs For Constipation	-	-	-	-	-	-	-	-	-	-
	Drugs Used In Diabetes	-	-	-	-	-	-	-	-	-	-
	Mineral Supplements	1	7	-	-	3	20	-	-	4	7
	Other Alimentary Tract And Metabolism Products	1	7	2	13	-	-	-	-	3	5
	Stomatological Preparations	-	-	1	7	-	-	1	7	2	3
	Vitamins	9	60	10	67	6	40	8	53	33	55
Antiinfectives For Systemic Use	**Any Level 2 Codes**	2	13	4	27	2	13	1	7	9	15
	Antibacterials For Systemic Use	1	7	2	13	1	7	1	7	5	8
	Antimycotics For Systemic Use	-	-	-	-	-	-	1	7	1	2
	Antivirals For Systemic Use	-	-	-	-	-	-	-	-	-	-

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Vaccines	1	7	2	13	1	7	-	-	4	7
Antineoplastic And Immunomodulating Agents	**Any Level 2 Codes**	-	-	-	-	-	-	-	-	-	-
	Antineoplastic Agents	-	-	-	-	-	-	-	-	-	-
	Endocrine Therapy	-	-	-	-	-	-	-	-	-	-
Blood And Blood Forming Organs	**Any Level 2 Codes**	1	7	-	-	2	13	3	20	6	10
	Antianemic Preparations	1	7	-	-	2	13	1	7	4	7
	Antithrombotic Agents	-	-	-	-	-	-	1	7	1	2
	Blood Substitutes And Perfusion Solutions	-	-	-	-	-	-	1	7	1	2
Cardiovascular System	**Any Level 2 Codes**	2	13	-	-	-	-	1	7	3	5
	Agents Acting On The Renin-Angiotensin System	-	-	-	-	-	-	-	-	-	-
	Beta Blocking Agents	-	-	-	-	-	-	-	-	-	-
	Calcium Channel Blockers	-	-	-	-	-	-	-	-	-	-
	Cardiac Therapy	-	-	-	-	-	-	-	-	-	-
	Diuretics	2	13	-	-	-	-	-	-	2	3
	Lipid Modifying Agents	-	-	-	-	-	-	-	-	-	-
	Vasoprotectives	-	-	-	-	-	-	1	7	1	2
Dermatologicals	**Any Level 2 Codes**	4	27	5	33	2	13	4	27	15	25
	Anti-Acne Preparations	-	-	-	-	-	-	1	7	1	2
	Antibiotics And Chemotherapeutics For Dermatological Use	2	13	2	13	-	-	-	-	4	7
	Antifungals For Dermatological Use	1	7	-	-	1	7	1	7	3	5

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	1	7	-	-	1	7	2	3
	Antiseptics And Disinfectants	1	7	-	-	-	-	-	-	1	2
	Corticosteroids, Dermatological Preparations	1	7	1	7	-	-	-	-	2	3
	Emollients And Protectives	1	7	-	-	-	-	1	7	2	3
	Other Dermatological Preparations	-	-	3	20	1	7	1	7	5	8
	Preparations For Treatment Of Wounds And Ulcers	-	-	-	-	-	-	-	-	-	-
Genito Urinary System And Sex Hormones	**Any Level 2 Codes**	4	27	1	7	5	33	7	47	17	28
	Gynecological Antiinfectives And Antiseptics	1	7	-	-	-	-	1	7	2	3
	Other Gynecologicals	3	20	-	-	1	7	4	27	8	13
	Sex Hormones And Modulators Of The Genital System	1	7	1	7	4	27	3	20	9	15
	Urologicals	-	-	-	-	-	-	-	-	-	-
Musculo-Skeletal System	**Any Level 2 Codes**	11	73	7	47	11	73	9	60	38	63
	Antiinflammatory And Antirheumatic Products	11	73	7	47	11	73	9	60	38	63
	Drugs For Treatment Of Bone Diseases	-	-	-	-	-	-	-	-	-	-
	Muscle Relaxants	-	-	-	-	1	7	-	-	1	2

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Other Drugs For Disorders Of The Musculo-Skeletal System	-	-	-	-	-	-	-	-	-	-
Nervous System	**Any Level 2 Codes**	8	53	10	67	6	40	11	73	35	58
	Analgesics	3	20	9	60	4	27	8	53	24	40
	Anesthetics	-	-	1	7	-	-	-	-	1	2
	Other Nervous System Drugs	-	-	-	-	-	-	-	-	-	-
	Psychoanaleptics	4	27	1	7	3	20	3	20	11	18
	Psycholeptics	3	20	3	20	-	-	2	13	8	13
Respiratory System	**Any Level 2 Codes**	9	60	6	40	5	33	6	40	26	43
	Antihistamines For Systemic Use	6	40	5	33	4	27	4	27	19	32
	Cough And Cold Preparations	-	-	1	7	-	-	1	7	2	3
	Drugs For Obstructive Airway Diseases	1	7	-	-	-	-	-	-	1	2
	Nasal Preparations	4	27	1	7	1	7	1	7	7	12
Sensory Organs	**Any Level 2 Codes**	2	13	-	-	-	-	-	-	2	3
	Ophthalmologicals	2	13	-	-	-	-	-	-	2	3
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	**Any Level 2 Codes**	1	7	1	7	-	-	-	-	2	3
	Corticosteroids For Systemic Use	-	-	1	7	-	-	-	-	1	2
	Thyroid Therapy	1	7	-	-	-	-	-	-	1	2
Various	**Any Level 2 Codes**	2	13	3	20	3	20	2	13	10	17
	General Nutrients	-	-	2	13	1	7	2	13	5	8

		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Unspecified Herbal And Traditional Medicine	2	13	2	13	2	13	-	-	6	10
N=Number of subjects in the Safety Population].n=Number of subjects reporting taking at least one medication in the specific WHO Drug Class.											

Table 173: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group All Subjects 56-70 Years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	WHO Drug Code Level 2, Therapeutic Group	n	%	n	%	n	%	n	%
Any Level 1 Codes	Any Level 2 Codes	10	100	10	100	10	100	30	100
Alimentary Tract And Metabolism	Any Level 2 Codes	7	70	5	50	5	50	17	57
	Antidiarrheals, Intestinal Antiinflammatory /Antiinfective Agents	-	-	2	20	-	-	2	7
	Antiemetics And Antinauseants	-	-	-	-	-	-	-	-
	Digestives, Incl. Enzymes	-	-	-	-	-	-	-	-
	Drugs For Acid Related Disorders	1	10	2	20	-	-	3	10
	Drugs For Constipation	-	-	-	-	-	-	-	-
	Drugs Used In Diabetes	-	-	-	-	-	-	-	-
	Mineral Supplements	1	10	2	20	2	20	5	17
	Other Alimentary Tract And Metabolism Products	-	-	-	-	-	-	-	-
	Stomatological Preparations	-	-	-	-	-	-	-	-
	Vitamins	6	60	5	50	5	50	16	53
Antiinfectives For Systemic Use	Any Level 2 Codes	3	30	6	60	4	40	13	43
	Antibacterials For Systemic Use	-	-	2	20	1	10	3	10
	Antimycotics For Systemic Use	1	10	-	-	-	-	1	3
	Antivirals For Systemic Use	2	20	-	-	2	20	4	13

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Vaccines	-	-	4	40	2	20	6	20
Antineoplastic And Immunomodulating Agents	**Any Level 2 Codes**	-	-	-	-	-	-	-	-
	Antineoplastic Agents	-	-	-	-	-	-	-	-
	Endocrine Therapy	-	-	-	-	-	-	-	-
Blood And Blood Forming Organs	**Any Level 2 Codes**	2	20	2	20	1	10	5	17
	Antianemic Preparations	-	-	1	10	-	-	1	3
	Antithrombotic Agents	2	20	1	10	1	10	4	13
	Blood Substitutes And Perfusion Solutions	-	-	-	-	-	-	-	-
Cardiovascular System	**Any Level 2 Codes**	6	60	4	40	3	30	13	43
	Agents Acting On The Renin-Angiotensin System	3	30	1	10	2	20	6	20
	Beta Blocking Agents	1	10	1	10	-	-	2	7
	Calcium Channel Blockers	-	-	1	10	1	10	2	7
	Cardiac Therapy	1	10	-	-	-	-	1	3
	Diuretics	-	-	1	10	1	10	2	7
	Lipid Modifying Agents	2	20	2	20	1	10	5	17
	Vasoprotectives	-	-	-	-	-	-	-	-
Dermatologicals	**Any Level 2 Codes**	2	20	3	30	1	10	6	20
	Anti-Acne Preparations	-	-	-	-	-	-	-	-
	Antibiotics And Chemotherapeutics For Dermatological Use	1	10	1	10	-	-	2	7
	Antifungals For Dermatological Use	-	-	1	10	-	-	1	3

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	-	-	-	-	-	-
	Antiseptics And Disinfectants	-	-	-	-	-	-	-	-
	Corticosteroids, Dermatological Preparations	-	-	-	-	1	10	1	3
	Emollients And Protectives	-	-	-	-	-	-	-	-
	Other Dermatological Preparations	1	10	1	10	-	-	2	7
	Preparations For Treatment Of Wounds And Ulcers	-	-	-	-	1	10	1	3
Genito Urinary System And Sex Hormones	**Any Level 2 Codes**	1	10	3	30	1	10	5	17
	Gynecological Antiinfectives And Antiseptics	-	-	-	-	-	-	-	-
	Other Gynecologicals	-	-	-	-	-	-	-	-
	Sex Hormones And Modulators Of The Genital System	1	10	1	10	1	10	3	10
	Urologicals	-	-	2	20	-	-	2	7
Musculo-Skeletal System	**Any Level 2 Codes**	6	60	7	70	7	70	20	67
	Antiinflammatory And Antirheumatic Products	6	60	7	70	7	70	20	67
	Drugs For Treatment Of Bone Diseases	2	20	1	10	1	10	4	13
	Muscle Relaxants	-	-	-	-	-	-	-	-

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Other Drugs For Disorders Of The Musculo-Skeletal System	-	-	-	-	-	-	-	-
Nervous System	**Any Level 2 Codes**	6	60	5	50	6	60	17	57
	Analgesics	4	40	5	50	3	30	12	40
	Anesthetics	-	-	-	-	1	10	1	3
	Other Nervous System Drugs	1	10	-	-	-	-	1	3
	Psychoanaleptics	2	20	1	10	2	20	5	17
	Psycholeptics	4	40	2	20	1	10	7	23
Respiratory System	**Any Level 2 Codes**	4	40	5	50	3	30	12	40
	Antihistamines For Systemic Use	3	30	5	50	3	30	11	37
	Cough And Cold Preparations	-	-	-	-	-	-	-	-
	Drugs For Obstructive Airway Diseases	-	-	-	-	1	10	1	3
	Nasal Preparations	2	20	2	20	2	20	6	20
Sensory Organs	**Any Level 2 Codes**	-	-	3	30	-	-	3	10
	Ophthalmologicals	-	-	3	30	-	-	3	10
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	**Any Level 2 Codes**	1	10	-	-	2	20	3	10
	Corticosteroids For Systemic Use	-	-	-	-	1	10	1	3
	Thyroid Therapy	1	10	-	-	1	10	2	7
Various	**Any Level 2 Codes**	4	40	1	10	1	10	6	20
	General Nutrients	2	20	-	-	1	10	3	10

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Unspecified Herbal And Traditional Medicine	2	20	1	10	1	10	4	13
N=Number of subjects in the Safety Population].n=Number of subjects reporting taking at least one medication in the specific WHO Drug Class.									

Table 174: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group
All Subjects ≥71 years of Age

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Level 1 Codes	**Any Level 2 Codes**	10	100	10	100	10	100	30	100
Alimentary Tract And Metabolism	**Any Level 2 Codes**	8	80	9	90	8	80	25	83
	Antidiarrheals, Intestinal Antiinflammatory /Antiinfective Agents	1	10	-	-	1	10	2	7
	Antiemetics And Antinauseants	-	-	-	-	-	-	-	-
	Digestives, Incl. Enzymes	-	-	-	-	-	-	-	-
	Drugs For Acid Related Disorders	5	50	3	30	5	50	13	43
	Drugs For Constipation	-	-	1	10	-	-	1	3
	Drugs Used In Diabetes	-	-	1	10	-	-	1	3
	Mineral Supplements	4	40	3	30	4	40	11	37
	Other Alimentary Tract And Metabolism Products	2	20	-	-	3	30	5	17
	Stomatological Preparations	1	10	-	-	-	-	1	3
	Vitamins	5	50	8	80	6	60	19	63
Antiinfectives For Systemic Use	**Any Level 2 Codes**	1	10	7	70	2	20	10	33
	Antibacterials For Systemic Use	-	-	1	10	1	10	2	7
	Antimycotics For Systemic Use	-	-	-	-	-	-	-	-
	Antivirals For Systemic Use	-	-	-	-	1	10	1	3

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Vaccines	1	10	7	70	-	-	8	27
Antineoplastic And Immunomodulating Agents	**Any Level 2 Codes**	-	-	1	10	1	10	2	7
	Antineoplastic Agents	-	-	-	-	1	10	1	3
	Endocrine Therapy	-	-	1	10	-	-	1	3
Blood And Blood Forming Organs	**Any Level 2 Codes**	1	10	3	30	3	30	7	23
	Antianemic Preparations	-	-	1	10	1	10	2	7
	Antithrombotic Agents	1	10	2	20	2	20	5	17
	Blood Substitutes And Perfusion Solutions	-	-	-	-	-	-	-	-
Cardiovascular System	**Any Level 2 Codes**	4	40	8	80	3	30	15	50
	Agents Acting On The Renin-Angiotensin System	2	20	4	40	2	20	8	27
	Beta Blocking Agents	-	-	-	-	-	-	-	-
	Calcium Channel Blockers	-	-	2	20	-	-	2	7
	Cardiac Therapy	1	10	-	-	1	10	2	7
	Diuretics	1	10	1	10	-	-	2	7
	Lipid Modifying Agents	3	30	6	60	1	10	10	33
	Vasoprotectives	-	-	-	-	-	-	-	-
Dermatologicals	**Any Level 2 Codes**	4	40	4	40	3	30	11	37
	Anti-Acne Preparations	-	-	-	-	1	10	1	3
	Antibiotics And Chemotherapeutics For Dermatological Use	2	20	1	10	-	-	3	10
	Antifungals For Dermatological Use	1	10	-	-	-	-	1	3

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	-	-	-	-	-	-
	Antiseptics And Disinfectants	-	-	-	-	-	-	-	-
	Corticosteroids, Dermatological Preparations	3	30	2	20	2	20	7	23
	Emollients And Protectives	-	-	1	10	-	-	1	3
	Other Dermatological Preparations	-	-	-	-	-	-	-	-
	Preparations For Treatment Of Wounds And Ulcers	-	-	-	-	-	-	-	-
Genito Urinary System And Sex Hormones	**Any Level 2 Codes**	3	30	3	30	-	-	6	20
	Gynecological Antiinfectives And Antiseptics	-	-	-	-	-	-	-	-
	Other Gynecologicals	-	-	-	-	-	-	-	-
	Sex Hormones And Modulators Of The Genital System	-	-	-	-	-	-	-	-
	Urologicals	3	30	3	30	-	-	6	20
Musculo-Skeletal System	**Any Level 2 Codes**	6	60	7	70	5	50	18	60
	Antiinflammatory And Antirheumatic Products	6	60	7	70	5	50	18	60
	Drugs For Treatment Of Bone Diseases	-	-	-	-	-	-	-	-
	Muscle Relaxants	-	-	-	-	-	-	-	-

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Other Drugs For Disorders Of The Musculo-Skeletal System	-	-	1	10	-	-	1	3
Nervous System	**Any Level 2 Codes**	9	90	5	50	5	50	19	63
	Analgesics	7	70	3	30	4	40	14	47
	Anesthetics	-	-	-	-	1	10	1	3
	Other Nervous System Drugs	-	-	-	-	1	10	1	3
	Psychoanaleptics	1	10	1	10	-	-	2	7
	Psycholeptics	3	30	1	10	-	-	4	13
Respiratory System	**Any Level 2 Codes**	3	30	5	50	4	40	12	40
	Antihistamines For Systemic Use	1	10	2	20	3	30	6	20
	Cough And Cold Preparations	-	-	-	-	-	-	-	-
	Drugs For Obstructive Airway Diseases	-	-	-	-	-	-	-	-
	Nasal Preparations	3	30	4	40	1	10	8	27
Sensory Organs	**Any Level 2 Codes**	1	10	5	50	-	-	6	20
	Ophthalmologicals	1	10	5	50	-	-	6	20
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	**Any Level 2 Codes**	-	-	-	-	-	-	-	-
	Corticosteroids For Systemic Use	-	-	-	-	-	-	-	-
	Thyroid Therapy	-	-	-	-	-	-	-	-
Various	**Any Level 2 Codes**	3	30	1	10	3	30	7	23
	General Nutrients	-	-	-	-	3	30	3	10

		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Unspecified Herbal And Traditional Medicine	3	30	1	10	1	10	5	17
N=Number of subjects in the Safety Population].n=Number of subjects reporting taking at least one medication in the specific WHO Drug Class.									

Figure 1: CONSORT Flow Diagram - 18-55 Years Old

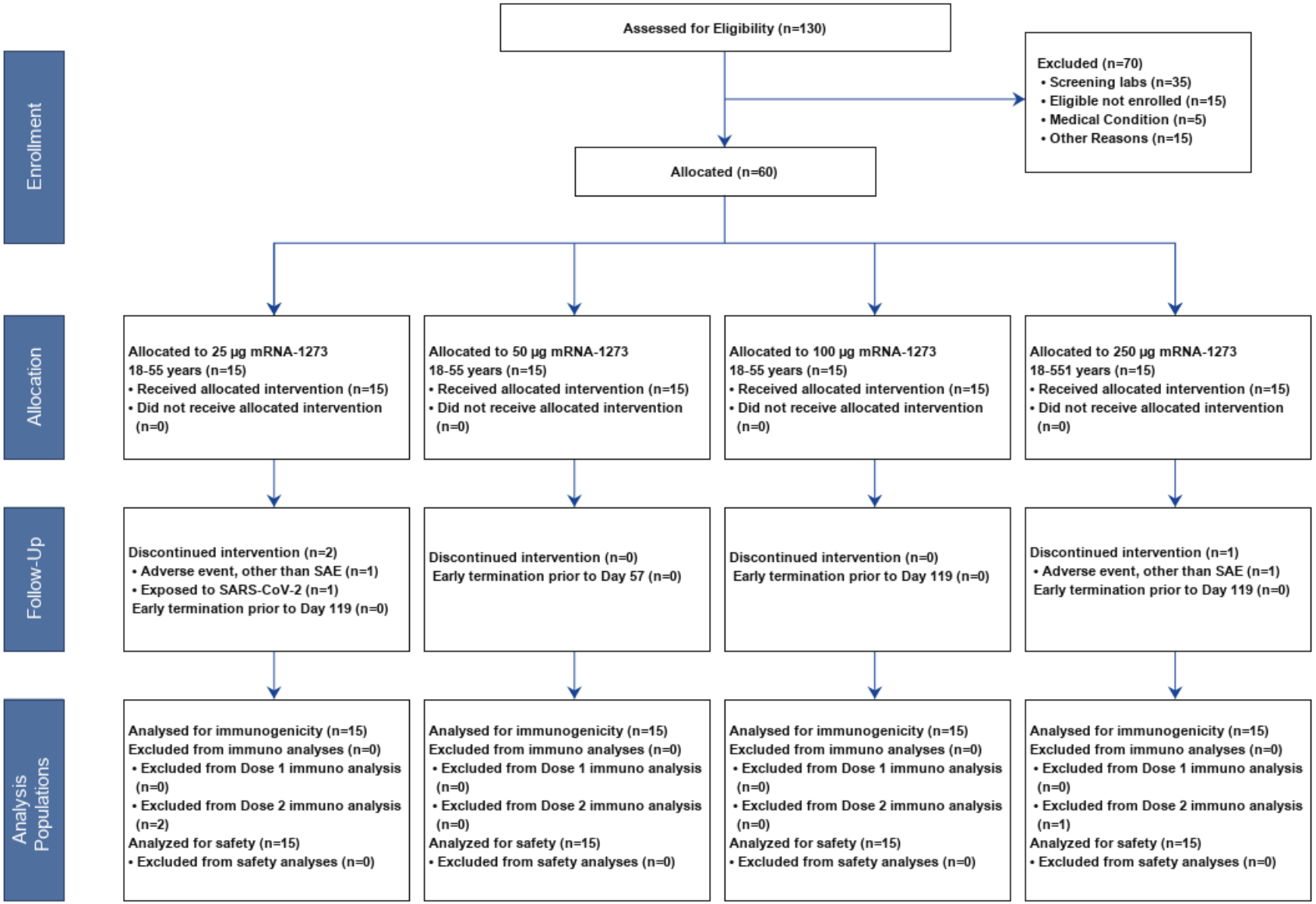


Figure 2: CONSORT Flow Diagram - 56-70 Years Old

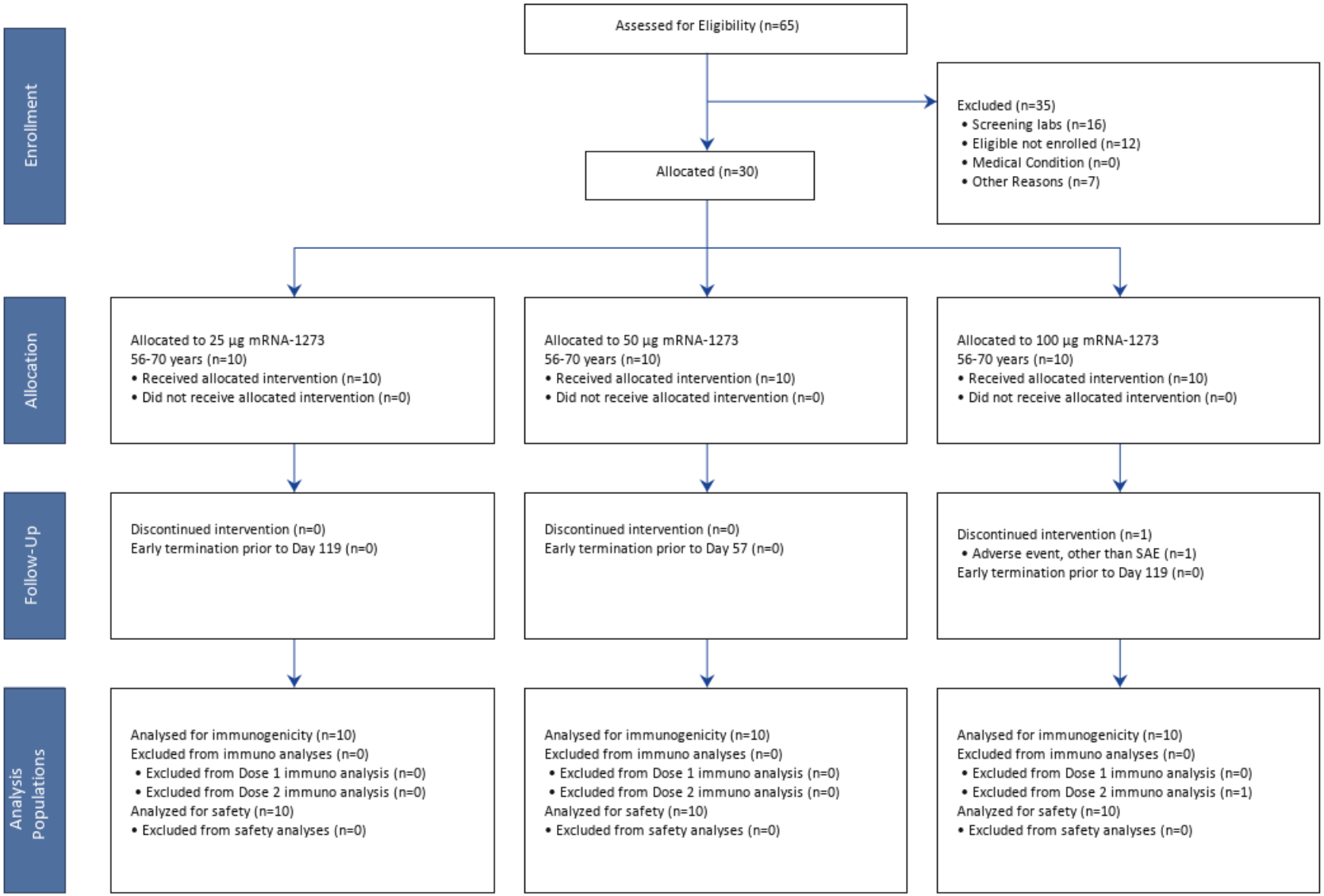


Figure 3: CONSORT Flow Diagram - ≥71 Years Old

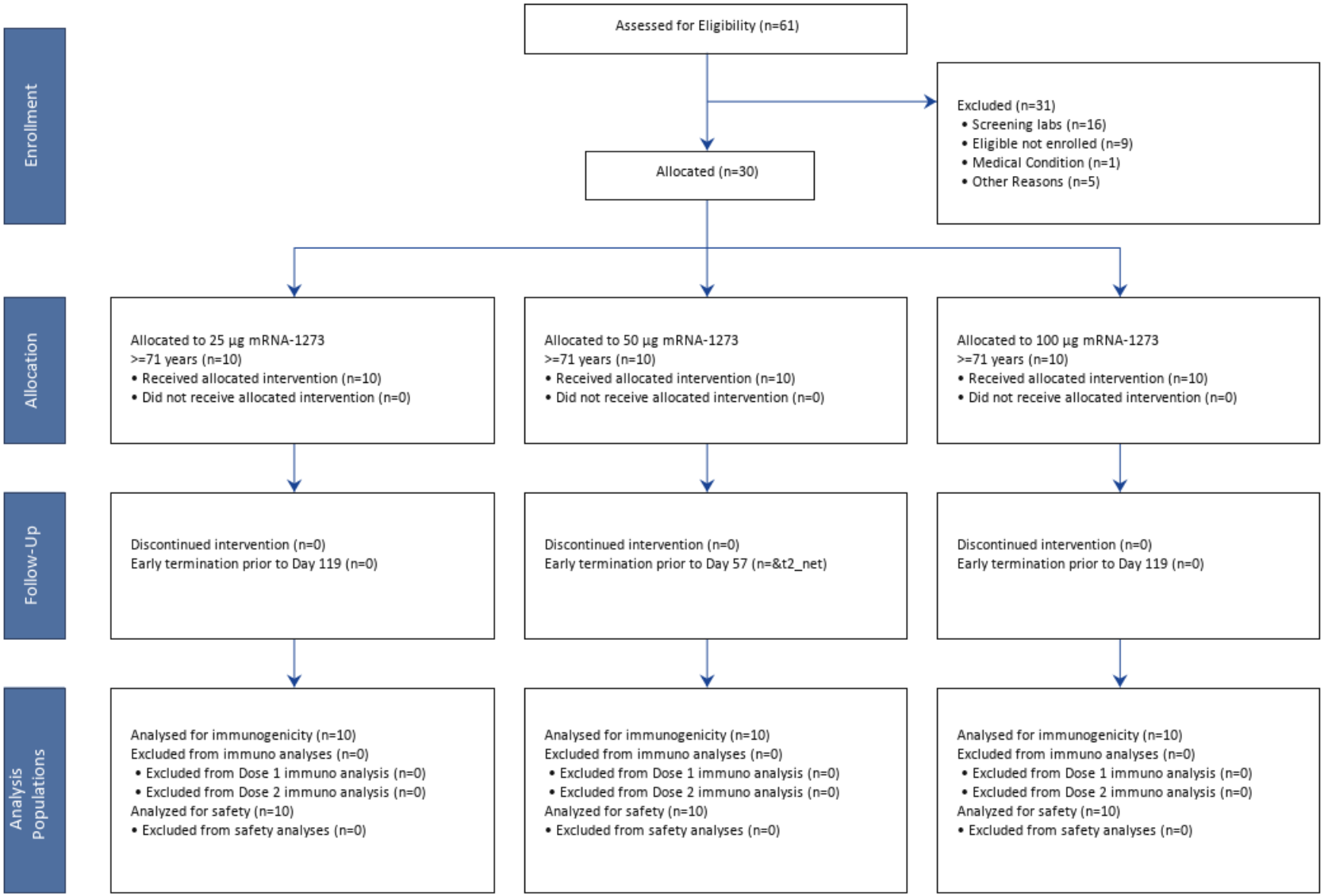


TABLE 15:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GMT	116	341	131	178	174	138901
	95% CI	72, 187	127, 914	65, 266	81, 392	121, 251	82876, 232799
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GMT	32261	67403	86291	163449	74418	
	95% CI	18723, 55587	32438, 140056	56403, 132016	102155, 261520	55452, 99870	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GMT	40227	118294	109209	213526	101369	
	95% CI	29094, 55621	71948, 194495	79051, 150874	128832, 353896	79236, 129685	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GMT	391018	866617	781399	1261975	771364	
	95% CI	267402, 571780	641450, 1170823	606247, 1007156	973972, 1635140	648287, 917807	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GMT	379764	734025	811119	994629	696133	
	95% CI	281597, 512152	588266, 915900	656336, 1002404	806189, 1227115	602999, 803652	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GMT	299751	562064	782719	1255376	645070	
	95% CI	206070, 436020	407368, 775505	619310, 989244	969516, 1625521	531541, 782848	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GMT	301540		413971	604507	425777	
	95% CI	217148, 418729		322891, 530744	451387, 809568	357332, 507332	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable							

TABLE 16:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	189	563	655	411	138901
	95% CI	76, 466	316, 1006	270, 1591	261, 649	82876, 232799
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	10509	43985	55532	29498	
	95% CI	2841, 38868	20837, 92849	40611, 75935	17406, 49992	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	17684	44878	115831	45131	
	95% CI	5300, 59001	23417, 86006	73288, 183069	27073, 75236	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	313720	201990	5033017	637766	
	95% CI	160451, 613395	99732, 409099	1113760, 22743909	306259, 1328109	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	476136	419777	1305996	623535	
	95% CI	263956, 858874	303166, 581241	581138, 2934971	438214, 887230	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	323945	315031	1183066	479594	
	95% CI	182202, 575958	217897, 455465	379698, 3686201	310929, 739751	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GMT	86391		366252	171244	
	95% CI	51215, 145728		213031, 629675	104822, 279757	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 17:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	111	325	953	325	138901
	95% CI	55, 222	104, 1015	493, 1842	188, 561	82876, 232799
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	14837	6720	104909	21869	
	95% CI	6925, 31787	1734, 26038	22445, 490343	10094, 47380	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	57986	16197	203365	57590	
	95% CI	31452, 106905	5220, 50257	97384, 424686	32150, 103160	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	460094	96574	2636979	489333	
	95% CI	272951, 775548	39656, 235186	1072782, 6481893	255624, 936714	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	303630	251461	8091439	851688	
	95% CI	167743, 549597	119950, 527158	2546249, 25712881	404186, 1794648	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	1128391	157016	3638522	863858	
	95% CI	636087, 2001717	82004, 300641	1316233, 10058130	461325, 1617623	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GMT	75677		195272	121563	
	95% CI	53020, 108016		117647, 324112	84822, 174220	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 18:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	56
	GMT	56	588	166	576	236	34648
	95% CI	44, 70	411, 840	82, 337	349, 949	169, 331	21443, 55985
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GMT	6567	27297	34073	87480	27037	
	95% CI	3651, 11813	15907, 46843	21688, 53531	51868, 147544	19239, 37995	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GMT	18149	66630	93231	120088	59961	
	95% CI	11091, 29700	35968, 123430	59895, 145123	71013, 203077	44203, 81336	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GMT	208652	659829	499539	720907	481983	
	95% CI	142803, 304864	466377, 933523	400950, 622370	591860, 878090	401121, 579145	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GMT	233264	572950	558905	644395	474371	
	95% CI	164756, 330259	398765, 823221	462908, 674810	495808, 837510	399349, 563487	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GMT	183652	515720	371271	564241	382295	
	95% CI	122763, 274741	328463, 809732	266721, 516804	396948, 802039	309541, 472150	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GMT	140985		235228	224653	197705	
	95% CI	79938, 248653		177236, 312195	151320, 333524	156955, 249036	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable							

TABLE 19:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	204	349	223	251	37244
	95% CI	114, 365	165, 737	64, 775	158, 399	20170, 68771
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	2924	8405	30981	9132	
	95% CI	576, 14833	5860, 12056	15901, 60362	4828, 17269	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	4841	13600	45690	14436	
	95% CI	1531, 15304	7948, 23271	26314, 79330	8476, 24586	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	198643	105925	1471882	297747	
	95% CI	98719, 399707	50968, 220142	560108, 3867893	166078, 533806	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	201496	244967	1005639	354975	
	95% CI	115918, 350251	154504, 388398	445521, 2269948	235731, 534538	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	78045	201801	506364	193486	
	95% CI	42847, 142159	135928, 299598	235654, 1088051	127566, 293473	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GMT	45421		151761	80431	
	95% CI	23045, 89526		88571, 260033	49072, 131830	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 20:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	111	194	503	221	37244
	95% CI	46, 270	92, 408	174, 1455	132, 370	20170, 68771
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	4676	2135	25670	6352	
	95% CI	2236, 9777	514, 8871	12394, 53168	3328, 12123	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	15338	8245	56343	19243	
	95% CI	7085, 33203	2487, 27335	35052, 90567	11299, 32771	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	160591	78965	711752	208206	
	95% CI	82611, 312177	25685, 242760	368657, 1374153	120213, 360610	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	295194	127341	694471	296649	
	95% CI	167293, 520878	44080, 367871	465032, 1037111	188585, 466637	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	218268	121389	453506	229043	
	95% CI	106743, 446314	43515, 338622	255624, 804573	146129, 359004	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GMT	65987		157946	102090	
	95% CI	33240, 130995		94345, 264420	65789, 158421	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 21:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GM	1	7	1	1	2	14157
	95% CI	0, 1	2, 22	0, 4	0, 5	1, 3	7616, 26312
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GM	5674	11200	19068	30642	13881	
	95% CI	3224, 9983	6140, 20431	12424, 29265	18029, 52078	10356, 18607	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GM	8304	15767	20525	38448	17699	
	95% CI	5221, 13209	8969, 27716	14234, 29595	22899, 64555	13623, 22993	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	94988	141838	213076	315723	175366	
	95% CI	64997, 138817	99921, 201339	165185, 274852	255688, 389853	146363, 210117	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GM	91081	146045	221956	254374	167352	
	95% CI	61317, 135293	102400, 208290	182108, 270524	200737, 322342	140601, 199193	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GM	77904	105398	147332	217813	128097	
	95% CI	56717, 107006	73793, 150539	113898, 190580	170240, 278681	108110, 151778	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GM	42487		81372	88852	68526	
	95% CI	29443, 61310		61678, 107354	66277, 119115	56531, 83066	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point.							

TABLE 22:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	2	12	9	6	14157
	95% CI	0, 5	4, 30	1, 37	3, 11	7616, 26312
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GM	702	6183	9822	3494	
	95% CI	103, 4751	2881, 13271	6539, 14753	1649, 7400	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	2037	6847	20493	6588	
	95% CI	496, 8355	3454, 13570	14413, 29137	3656, 11869	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GM	45869	33012	1070250	108844	
	95% CI	23165, 90823	17514, 62224	224760, 5096239	50021, 236839	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GM	64533	78050	277751	108388	
	95% CI	34146, 121959	55858, 109059	115183, 669765	72488, 162068	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GM	49990	70851	266183	94736	
	95% CI	27060, 92349	54739, 91706	94155, 752518	61197, 146656	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GM	16624		62227	31065	
	95% CI	9084, 30422		39421, 98228	19315, 49963	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 23:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	1	6	15	5	14157
	95% CI	0, 3	1, 25	6, 39	2, 10	7616, 26312
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GM	1664	661	16174	2612	
	95% CI	679, 4076	138, 3144	3350, 78072	1103, 6185	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	5949	2073	23933	6658	
	95% CI	2934, 12061	608, 7067	10375, 55204	3614, 12265	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GM	95566	16091	557510	94999	
	95% CI	57468, 158922	6431, 40257	191748, 1620960	47126, 191502	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GM	70620	48716	1273343	163625	
	95% CI	41797, 119320	22221, 106801	403930, 4014062	81035, 330389	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GM	142653	40430	523632	144545	
	95% CI	66931, 304041	20221, 80832	167243, 1639475	79535, 262692	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GM	18687		48171	30003	
	95% CI	12303, 28385		29102, 79735	20677, 43537	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 24:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	56
	GM	0	9	2	14	3	4365
	95% CI	0, 0	5, 16	0, 4	6, 33	2, 6	2446, 7788
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GM	596	4523	5642	15337	3910	
	95% CI	258, 1376	2479, 8252	3130, 10170	9094, 25866	2555, 5983	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GM	2110	9202	12130	17556	7913	
	95% CI	1130, 3939	4941, 17137	8447, 17418	10869, 28358	5734, 10920	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	43973	104431	126250	200639	105802	
	95% CI	30848, 62681	71079, 153431	91696, 173824	160276, 251167	86107, 130001	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GM	45792	110554	141713	170112	106706	
	95% CI	30246, 69327	74467, 164130	110096, 182410	133715, 216415	87238, 130517	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GM	55071	81161	106248	113627	86303	
	95% CI	36135, 83930	54190, 121557	76429, 147701	82246, 156983	71807, 103727	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GM	25750		45905	43401	37672	
	95% CI	14395, 46060		32315, 65210	30790, 61179	29669, 47835	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable							

TABLE 25:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	2	8	3	4	4222
	95% CI	1, 5	2, 28	0, 10	2, 7	2021, 8819
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GM	161	1109	3817	880	
	95% CI	18, 1341	718, 1712	2303, 6327	390, 1986	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	522	2187	10045	2256	
	95% CI	91, 2970	1147, 4171	5718, 17645	1091, 4664	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GM	31501	23593	301411	57469	
	95% CI	14520, 68343	12720, 43758	101394, 895996	31550, 104681	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GM	41848	56750	248702	80817	
	95% CI	21034, 83258	37471, 85949	109350, 565638	52054, 125472	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GM	24347	44732	109975	47948	
	95% CI	13051, 45416	31318, 63891	66446, 182018	33877, 67863	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GM	9828		36516	18302	
	95% CI	4667, 20697		22002, 60604	10822, 30950	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 26:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD -Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	1	3	6	3	4222
	95% CI	0, 5	1, 10	1, 24	1, 6	2021, 8819
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GM	317	108	3007	469	
	95% CI	122, 825	14, 792	1219, 7417	196, 1121	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	2354	728	8229	2417	
	95% CI	935, 5927	145, 3644	4332, 15630	1220, 4788	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GM	44554	14239	153562	46014	
	95% CI	24426, 81270	4940, 41038	72220, 326519	26382, 80256	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GM	48343	31589	111806	55477	
	95% CI	26849, 87043	11858, 84151	69029, 181092	36739, 83773	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GM	41781	25439	95909	46714	
	95% CI	23064, 75689	9476, 68291	57611, 159664	30652, 71191	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GM	11062		29736	18137	
	95% CI	5901, 20739		17627, 50162	11704, 28106	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 27:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GMT	10	10	10	10	10	106
	95% CI	NE	NE	NE	NE	NE	60, 189
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GMT	14	23	24	26	21	
	95% CI	10, 21	13, 40	13, 42	14, 48	16, 27	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GMT	12	14	18	21	16	
	95% CI	10, 14	9, 21	12, 27	13, 32	13, 19	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GMT	106	294	263	378	241	
	95% CI	70, 160	178, 487	188, 368	306, 468	194, 298	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GMT	112	351	360	342	268	
	95% CI	71, 177	214, 575	273, 476	267, 438	216, 333	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GMT	90	234	276	277	204	
	95% CI	57, 143	153, 358	193, 393	231, 332	166, 251	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GMT	54		182	185	126	
	95% CI	29, 100		112, 296	128, 269	92, 173	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable							

TABLE 28:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	10	10	10	10	106
	95% CI	NE	NE	NE	NE	60, 189
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	10	12	12	11	
	95% CI	NE	10, 14	10, 15	10, 12	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	10	12	11	11	
	95% CI	NE	9, 16	10, 12	10, 12	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	85	108	340	142	
	95% CI	51, 142	56, 211	219, 527	99, 204	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	119	220	404	215	
	95% CI	68, 209	162, 299	292, 561	162, 286	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	100	163	424	185	
	95% CI	49, 204	115, 230	267, 673	130, 264	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GMT	44		167	83	
	95% CI	20, 98		88, 318	47, 146	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 29:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	10	10	10	10	106
	95% CI	NE	NE	NE	NE	60, 189
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	11	10	27	15	
	95% CI	9, 14	NE	12, 60	11, 19	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	11	12	20	14	
	95% CI	9, 12	9, 17	12, 33	11, 17	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	121	75	310	141	
	95% CI	69, 211	30, 190	202, 475	94, 212	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	112	217	317	197	
	95% CI	67, 188	86, 542	198, 508	136, 287	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	100	150	231	151	
	95% CI	56, 179	53, 419	150, 356	103, 223	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GMT	33		109	60	
	95% CI	19, 59		68, 175	39, 93	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 30:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GMT	10	10	10	10	10	41
	95% CI	NE	NE	NE	NE	NE	26, 66
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60	
	GMT	11	11	13	13	12	
	95% CI	9, 13	9, 13	8, 19	10, 18	11, 14	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GMT	10	12	10	12	11	
	95% CI	NE	9, 14	10, 11	10, 16	10, 12	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57	
	GMT	53	130	134	158	112	
	95% CI	34, 83	88, 192	96, 188	131, 190	93, 136	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GMT	60	160	164	153	126	
	95% CI	37, 96	98, 262	122, 219	122, 193	103, 155	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56	
	GMT	52	109	145	123	102	
	95% CI	31, 87	70, 168	102, 205	94, 160	83, 125	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42	
	GMT	29		80	83	59	
	95% CI	17, 50		52, 122	58, 119	45, 78	

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable							

TABLE 31:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	10	10	10	10	41
	95% CI	NE	NE	NE	NE	26, 66
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	10	10	10	10	
	95% CI	NE	NE	NE	NE	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	10	10	10	10	
	95% CI	NE	NE	NE	NE	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	41	50	166	68	
	95% CI	21, 79	25, 99	99, 279	46, 101	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	53	102	204	101	
	95% CI	28, 98	77, 133	146, 284	74, 137	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	42	74	140	74	
	95% CI	21, 85	52, 106	89, 221	54, 103	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19	
	GMT	24		70	40	
	95% CI	12, 46		45, 109	25, 62	

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 32:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age ≥71 Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GMT	10	10	10	10	41
	95% CI	NE	NE	NE	NE	26, 66
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30	
	GMT	10	10	12	11	
	95% CI	NE	NE	10, 15	10, 11	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GMT	10	10	11	10	
	95% CI	NE	NE	9, 14	10, 11	
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	58	28	140	61	
	95% CI	34, 99	11, 69	82, 239	40, 93	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	61	74	194	96	
	95% CI	34, 110	26, 210	121, 311	63, 146	
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30	
	GMT	47	55	117	67	
	95% CI	25, 87	19, 158	74, 184	45, 101	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20	
	GMT	15		52	28	
	95% CI	10, 23		32, 87	19, 43	

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)	Convalescent Sera
Note: N=Number of Subjects. n=Number of subjects with results available at time point. NE=Not Estimable						

TABLE 33:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50}, Per Protocol Population

Variant	Time Point	Statistic	100 mcg mRNA-1273 18-55 years (N=15)	100 mcg mRNA-1273 56-70 years (N=10)	100 mcg mRNA-1273 ≥71 years (N=10)
614D	**Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)**	n	14	9	10
		GMT	360	402	317
		95% CI	273, 476	289, 560	198, 508
614G	**Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)**	n	14	9	10
		GMT	1796	1878	1456
		95% CI	1350, 2391	1259, 2801	895, 2368

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.

TABLE 34:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80}, Per Protocol Population

Variant	Time Point	Statistic	100 mcg mRNA-1273 18-55 years (N=15)	100 mcg mRNA-1273 56-70 years (N=10)	100 mcg mRNA-1273 ≥71 years (N=10)
614D	**Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)**	n	14	9	10
		GMT	164	203	194
		95% CI	122, 219	145, 283	121, 311
614G	**Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)**	n	14	9	10
		GMT	620	644	482
		95% CI	457, 841	427, 971	296, 787

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.

TABLE 35:
Plaque Reduction Neutralization Test Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=30)
Day 1 (Pre-Vaccination 1)	n	15	15	30
	GMT	4	4	4
	95% CI	NE	NE	NE
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	27
	GMT	340	654	477
	95% CI	184, 627	460, 930	337, 676
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n		15	15
	GMT		430	430
	95% CI		277, 667	277, 667

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 36:
Plaque Reduction Neutralization Test Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 56-70, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 56-70 years (N=10)
Day 1 **(Pre-Vaccination 1)**	n	10
	GMT	4
	95% CI	NE
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	9
	GMT	878
	95% CI	516, 1494
Day 119 Post Vaccination 1 **(90 Days Post Vaccination 2)**	n	9
	GMT	269
	95% CI	134, 542

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 37:
Plaque Reduction Neutralization Test Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 ≥71 years (N=10)
Day 1 **(Pre-Vaccination 1)**	n	10
	GMT	4
	95% CI	NE
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	10
	GMT	317
	95% CI	181, 557
Day 119 Post Vaccination 1 **(90 Days Post Vaccination 2)**	n	10
	GMT	165
	95% CI	82, 332

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 38:
FRNT Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50}, Per Protocol Population

Time Point	Statistic	25 mcg mRNA-1273 18-55 years (N=15)	100 mcg mRNA -1273 18-55 years (N=15)	18-55 years (N=30)
Day 1 (Pre-Vaccination 1)	n	15	15	30
	GMT	10.0	10.0	10.0
	95% CI	NE	NE	NE
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	30
	GMT	33.9	108.7	60.7
	95% CI	21.3, 54.0	78.9, 149.9	43.0, 85.8
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	27
	GMT	559.5	1165.4	818.5
	95% CI	363.4, 861.5	888.3, 1529.0	621.3, 1078.3

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 39:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	45	41
	GM	10	10	10	10	129
	95% CI	NE	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	14	44	
	GM	23	69	77	49	
	95% CI	13, 39	46, 102	43, 136	36, 67	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	41	
	GM	622	1388	1575	1123	
	95% CI	374, 1034	1056, 1825	1206, 2058	894, 1412	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13	15	14	42	
	GM	309	775	599	535	
	95% CI	184, 517	560, 1071	437, 821	422, 677	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 40:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	20	41
	GM	10	10	10	129
	95% CI	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	20	
	GM	19	80	39	
	95% CI	11, 32	52, 123	24, 62	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	9	19	
	GM	550	1425	863	
	95% CI	302, 1001	980, 2072	578, 1290	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	9	19	
	GM	227	685	383	
	95% CI	131, 392	436, 1077	251, 584	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 41:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	20	41
	GM	10	10	10	129
	95% CI	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	20	
	GM	18	39	27	
	95% CI	12, 29	18, 86	17, 42	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	20	
	GM	448	900	635	
	95% CI	299, 672	575, 1409	461, 874	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	20	
	GM	183	552	318	
	95% CI	123, 272	321, 947	213, 475	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 42:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	45	41
	GM	10	10	10	10	37
	95% CI	NE	NE	NE	NE	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	14	44	
	GM	12	25	20	18	
	95% CI	10, 15	18, 33	13, 32	15, 22	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	41	
	GM	234	525	487	396	
	95% CI	144, 381	416, 663	382, 619	322, 488	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13	15	14	42	
	GM	89	237	196	164	
	95% CI	49, 160	170, 332	143, 270	127, 212	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 43:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	20	41
	GM	10	10	10	37
	95% CI	NE	NE	NE	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	20	
	GM	10	17	13	
	95% CI	NE	11, 25	10, 16	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	9	19	
	GM	167	583	302	
	95% CI	101, 277	400, 851	198, 461	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	9	19	
	GM	71	233	124	
	95% CI	34, 148	145, 375	75, 205	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 44:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	20	41
	GM	10	10	10	37
	95% CI	NE	NE	NE	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	20	
	GM	11	15	13	
	95% CI	9, 14	9, 25	10, 17	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	20	
	GM	169	392	258	
	95% CI	107, 268	252, 609	182, 365	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	20	
	GM	52	190	99	
	95% CI	30, 90	115, 317	63, 158	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 45:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	30	28
	GMT	10	10	10	46
	95% CI	-, -	-, -	-, -	31, 69
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	30	
	GMT	21	29	25	
	95% CI	13, 33	19, 44	19, 33	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	13	26	
	GMT	253	526	365	
	95% CI	145, 443	374, 739	260, 512	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 46:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age 56-70, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 56-70 years (N=10)	Convalescent Sera
Day 1 **(Pre-Vaccination 1)**	n	10	28
	GMT	20	46
	95% CI	-, -	31, 69
Day 29 Post Vaccination 1 **(Pre-Vaccination 2)**	n	10	
	GMT	21	
	95% CI	18, 25	
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	9	
	GMT	530	
	95% CI	337, 835	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 47:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} – Age ≥71, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 ≥71 years (N=10)	Convalescent Sera
Day 1 **(Pre-Vaccination 1)**	n	10	28
	GMT	20	46
	95% CI	-, -	31, 69
Day 29 Post Vaccination 1 **(Pre-Vaccination 2)**	n	10	
	GMT	24	
	95% CI	18, 32	
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	10	
	GMT	391	
	95% CI	235, 649	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 48:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	30	
	GMT	10	10	10	
	95% CI	-, -	-, -	-, -	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	14	15	29	
	GMT	20	32	26	
	95% CI	13, 30	22, 46	20, 34	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	13	26	
	GMT	246	646	399	
	95% CI	150, 403	472, 885	285, 558	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 49:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - Age 56-70, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 56-70 years (N=10)	Convalescent Sera
Day 1 **(Pre-Vaccination 1)**	n	10	
	GMT	20	
	95% CI	-, -	
Day 29 Post Vaccination 1 **(Pre-Vaccination 2)**	n	10	
	GMT	20	
	95% CI	-, -	
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	9	
	GMT	440	
	95% CI	276, 700	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 50:
nLuciferase Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} – Age ≥71, Per Protocol Population

Time Point	Statistic	100 µg mRNA-1273 ≥71 years (N=10)	Convalescent Sera
Day 1 **(Pre-Vaccination 1)**	n	10	
	GMT	20	
	95% CI	-, -	
Day 29 Post Vaccination 1 **(Pre-Vaccination 2)**	n	10	
	GMT	24	
	95% CI	18, 31	
Day 43 Post Vaccination 1 **(14 Days Post Vaccination 2)**	n	10	
	GMT	327	
	95% CI	196, 546	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 51:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th1 Response - Age 18-55, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th1**	n	15	15	30
			Mean	0.001	0.006	0.004
			95% CI	-0.004, 0.007	-0.001, 0.013	0.000, 0.008
		IFNγ	n	15	15	30
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
		IL-2	n	15	15	30
			Mean	-0.003	0.003	0.000
			95% CI	-0.008, 0.002	0.000, 0.005	-0.003, 0.003
		TNF	n	15	15	30
			Mean	0.004	0.007	0.005
			95% CI	-0.002, 0.010	0.001, 0.012	0.001, 0.009
	SARS-CoV-2 S2	**Any Th1**	n	15	15	30
			Mean	0.007	0.010	0.009
			95% CI	0.001, 0.014	0.006, 0.014	0.005, 0.012
		IFNγ	n	15	15	30
			Mean	0.004	0.004	0.004
			95% CI	0.001, 0.007	0.000, 0.008	0.002, 0.006
		IL-2	n	15	15	30
			Mean	0.002	0.003	0.003
			95% CI	-0.001, 0.005	0.001, 0.006	0.001, 0.005
		TNF	n	15	15	30
			Mean	0.008	0.011	0.009
			95% CI	0.001, 0.015	0.006, 0.015	0.006, 0.013

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	14	15	29
			Mean	0.030	0.065	0.048
			95% CI	0.014, 0.046	0.043, 0.087	0.034, 0.062
		IFNγ	n	14	15	29
			Mean	0.005	0.019	0.012
			95% CI	0.000, 0.010	0.012, 0.026	0.007, 0.017
		IL-2	n	14	15	29
			Mean	0.014	0.042	0.028
			95% CI	0.004, 0.024	0.026, 0.058	0.018, 0.039
		TNF	n	14	15	29
			Mean	0.026	0.058	0.043
			95% CI	0.013, 0.040	0.036, 0.080	0.029, 0.056
	SARS-CoV-2 S2	**Any Th1**	n	14	15	29
			Mean	0.025	0.060	0.043
			95% CI	0.017, 0.033	0.045, 0.075	0.033, 0.054
		IFNγ	n	14	15	29
			Mean	0.009	0.024	0.017
			95% CI	0.004, 0.013	0.014, 0.034	0.010, 0.023
		IL-2	n	14	15	29
			Mean	0.013	0.041	0.027
			95% CI	0.006, 0.019	0.029, 0.053	0.019, 0.036
		TNF	n	14	15	29
			Mean	0.026	0.055	0.041
			95% CI	0.018, 0.033	0.041, 0.070	0.031, 0.051
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	12	14	26
			Mean	0.106	0.216	0.165
			95% CI	0.059, 0.153	0.151, 0.281	0.121, 0.209

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
		IFNγ	n	12	14	26
			Mean	0.043	0.094	0.070
			95% CI	0.021, 0.066	0.063, 0.124	0.050, 0.091
		IL-2	n	12	14	26
			Mean	0.067	0.121	0.096
			95% CI	0.035, 0.098	0.075, 0.166	0.067, 0.125
		TNF	n	12	14	26
			Mean	0.095	0.191	0.147
			95% CI	0.051, 0.139	0.132, 0.251	0.106, 0.187
	SARS-CoV-2 S2	**Any Th1**	n	12	14	26
			Mean	0.098	0.241	0.175
			95% CI	0.061, 0.134	0.167, 0.316	0.125, 0.225
		IFNγ	n	12	14	26
			Mean	0.046	0.107	0.079
			95% CI	0.024, 0.067	0.074, 0.140	0.056, 0.102
		IL-2	n	12	14	26
			Mean	0.063	0.142	0.105
			95% CI	0.037, 0.088	0.093, 0.192	0.074, 0.137
		TNF	n	12	14	26
			Mean	0.094	0.218	0.161
			95% CI	0.059, 0.129	0.148, 0.288	0.115, 0.207

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 52:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th1 Response – Age 56-70, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th1**	n	9	9	18
			Mean	-0.001	0.008	0.003
			95% CI	-0.012, 0.010	-0.002, 0.018	-0.004, 0.010
		IFNγ	n	9	9	18
			Mean	-0.001	0.001	0.000
			95% CI	-0.004, 0.001	-0.001, 0.004	-0.002, 0.002
		IL-2	n	9	9	18
			Mean	0.000	-0.001	-0.001
			95% CI	-0.007, 0.007	-0.004, 0.001	-0.004, 0.003
		TNF	n	9	9	18
			Mean	-0.001	0.008	0.003
			95% CI	-0.011, 0.009	0.000, 0.015	-0.003, 0.009
	SARS-CoV-2 S2	**Any Th1**	n	9	9	18
			Mean	0.014	0.010	0.012
			95% CI	-0.006, 0.035	0.006, 0.014	0.003, 0.022
		IFNγ	n	9	9	18
			Mean	0.003	0.001	0.002
			95% CI	-0.002, 0.009	-0.001, 0.004	-0.001, 0.005
		IL-2	n	9	9	18
			Mean	0.012	0.002	0.007
			95% CI	-0.003, 0.027	-0.003, 0.007	0.000, 0.015
		TNF	n	9	9	18
			Mean	0.014	0.010	0.012
			95% CI	-0.003, 0.032	0.006, 0.014	0.004, 0.020

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	9	9	18
			Mean	0.037	0.102	0.069
			95% CI	0.020, 0.053	0.078, 0.126	0.048, 0.091
		IFNγ	n	9	9	18
			Mean	0.007	0.022	0.014
			95% CI	0.001, 0.012	0.012, 0.033	0.008, 0.021
		IL-2	n	9	9	18
			Mean	0.026	0.072	0.049
			95% CI	0.013, 0.038	0.052, 0.092	0.033, 0.065
		TNF	n	9	9	18
			Mean	0.033	0.096	0.064
			95% CI	0.017, 0.050	0.076, 0.115	0.045, 0.084
	SARS-CoV-2 S2	**Any Th1**	n	9	9	18
			Mean	0.031	0.093	0.062
			95% CI	0.021, 0.041	0.061, 0.126	0.040, 0.084
		IFNγ	n	9	9	18
			Mean	0.008	0.029	0.018
			95% CI	0.003, 0.013	0.011, 0.047	0.008, 0.028
		IL-2	n	9	9	18
			Mean	0.023	0.067	0.045
			95% CI	0.016, 0.031	0.041, 0.093	0.029, 0.061
		TNF	n	9	9	18
			Mean	0.030	0.089	0.059
			95% CI	0.020, 0.040	0.064, 0.114	0.040, 0.079
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	9	8	17
			Mean	0.264	0.336	0.298
			95% CI	0.096, 0.433	0.196, 0.476	0.198, 0.398

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
		IFNγ	n	9	8	17
			Mean	0.108	0.148	0.126
			95% CI	0.062, 0.153	0.101, 0.194	0.096, 0.157
		IL-2	n	9	8	17
			Mean	0.204	0.224	0.214
			95% CI	0.074, 0.335	0.122, 0.325	0.139, 0.288
		TNF	n	9	8	17
			Mean	0.224	0.296	0.258
			95% CI	0.085, 0.364	0.176, 0.416	0.174, 0.342
	SARS-CoV-2 S2	**Any Th1**	n	9	8	17
			Mean	0.263	0.344	0.301
			95% CI	0.097, 0.430	0.164, 0.524	0.192, 0.411
		IFNγ	n	9	8	17
			Mean	0.112	0.160	0.135
			95% CI	0.059, 0.166	0.088, 0.232	0.094, 0.175
		IL-2	n	9	8	17
			Mean	0.209	0.255	0.231
			95% CI	0.074, 0.344	0.109, 0.401	0.142, 0.319
		TNF	n	9	8	17
			Mean	0.236	0.314	0.272
			95% CI	0.092, 0.379	0.151, 0.477	0.175, 0.369

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 53:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th1 Response – Age ≥71, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th1**	n	10	10	20
			Mean	0.004	0.004	0.004
			95% CI	-0.004, 0.012	-0.002, 0.010	0.000, 0.008
		IFNγ	n	10	10	20
			Mean	-0.001	0.001	0.000
			95% CI	-0.005, 0.003	-0.001, 0.003	-0.002, 0.002
		IL-2	n	10	10	20
			Mean	0.005	0.000	0.003
			95% CI	0.000, 0.010	-0.003, 0.003	0.000, 0.005
		TNF	n	10	10	20
			Mean	0.004	0.004	0.004
			95% CI	0.000, 0.008	-0.001, 0.009	0.001, 0.007
	SARS-CoV-2 S2	**Any Th1**	n	10	10	20
			Mean	0.010	0.066	0.038
			95% CI	0.003, 0.017	-0.033, 0.165	-0.009, 0.085
		IFNγ	n	10	10	20
			Mean	0.001	0.017	0.009
			95% CI	-0.001, 0.003	-0.010, 0.044	-0.004, 0.022
		IL-2	n	10	10	20
			Mean	0.004	0.037	0.021
			95% CI	-0.003, 0.011	-0.022, 0.096	-0.007, 0.048
		TNF	n	10	10	20
			Mean	0.007	0.063	0.035
			95% CI	0.001, 0.013	-0.030, 0.156	-0.009, 0.079

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	10	10	20
			Mean	0.023	0.069	0.046
			95% CI	0.003, 0.043	0.022, 0.116	0.021, 0.071
		IFNγ	n	10	10	20
			Mean	0.001	0.016	0.009
			95% CI	-0.003, 0.005	0.003, 0.029	0.001, 0.016
		IL-2	n	10	10	20
			Mean	0.014	0.046	0.030
			95% CI	0.000, 0.028	0.012, 0.080	0.012, 0.048
		TNF	n	10	10	20
			Mean	0.023	0.066	0.045
			95% CI	0.003, 0.043	0.021, 0.111	0.020, 0.069
	SARS-CoV-2 S2	**Any Th1**	n	10	10	20
			Mean	0.028	0.058	0.043
			95% CI	0.008, 0.048	0.029, 0.087	0.026, 0.060
		IFNγ	n	10	10	20
			Mean	0.005	0.014	0.010
			95% CI	0.000, 0.010	0.006, 0.022	0.005, 0.014
		IL-2	n	10	10	20
			Mean	0.018	0.040	0.029
			95% CI	0.002, 0.034	0.021, 0.059	0.016, 0.042
		TNF	n	10	10	20
			Mean	0.031	0.057	0.044
			95% CI	0.011, 0.051	0.029, 0.085	0.027, 0.061
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th1**	n	10	10	20
			Mean	0.095	0.317	0.206
			95% CI	0.061, 0.129	0.162, 0.472	0.117, 0.295

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
		IFNγ	n	10	10	20
			Mean	0.031	0.164	0.098
			95% CI	0.016, 0.046	0.077, 0.251	0.047, 0.148
		IL-2	n	10	10	20
			Mean	0.065	0.214	0.140
			95% CI	0.042, 0.088	0.110, 0.318	0.079, 0.200
		TNF	n	10	10	20
			Mean	0.085	0.295	0.190
			95% CI	0.050, 0.120	0.145, 0.445	0.104, 0.276
	SARS-CoV-2 S2	**Any Th1**	n	10	10	20
			Mean	0.116	0.366	0.241
			95% CI	0.075, 0.157	0.166, 0.566	0.131, 0.351
		IFNγ	n	10	10	20
			Mean	0.039	0.198	0.119
			95% CI	0.025, 0.053	0.054, 0.342	0.043, 0.194
		IL-2	n	10	10	20
			Mean	0.081	0.271	0.176
			95% CI	0.053, 0.109	0.108, 0.434	0.089, 0.263
		TNF	n	10	10	20
			Mean	0.110	0.345	0.228
			95% CI	0.068, 0.152	0.148, 0.542	0.120, 0.335

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 54:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th2 Response – Age 18-55, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th2**	n	15	15	30
			Mean	0.002	0.000	0.001
			95% CI	-0.001, 0.005	-0.002, 0.002	-0.001, 0.003
		IL-13	n	15	15	30
			Mean	0.002	0.000	0.001
			95% CI	-0.001, 0.005	-0.002, 0.002	-0.001, 0.003
		IL-4	n	15	15	30
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	15	15	30
			Mean	0.001	0.002	0.001
			95% CI	-0.001, 0.002	-0.001, 0.005	0.000, 0.003
		IL-13	n	15	15	30
			Mean	0.001	0.001	0.001
			95% CI	-0.001, 0.002	-0.002, 0.004	-0.001, 0.003
		IL-4	n	15	15	30
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	14	15	29
			Mean	0.001	0.002	0.002
			95% CI	-0.002, 0.005	0.000, 0.004	0.000, 0.004
		IL-13	n	14	15	29
			Mean	0.001	0.002	0.002
			95% CI	-0.002, 0.005	0.000, 0.004	0.000, 0.004

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
		IL-4	n	14	15	29
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	14	15	29
			Mean	0.002	0.004	0.003
			95% CI	-0.001, 0.005	0.001, 0.007	0.001, 0.005
		IL-13	n	14	15	29
			Mean	0.001	0.003	0.002
			95% CI	-0.002, 0.003	0.000, 0.005	0.000, 0.004
		IL-4	n	14	15	29
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	12	14	26
			Mean	0.013	0.014	0.014
			95% CI	0.007, 0.020	0.006, 0.022	0.009, 0.019
		IL-13	n	12	14	26
			Mean	0.012	0.010	0.011
			95% CI	0.006, 0.018	0.004, 0.016	0.007, 0.015
		IL-4	n	12	14	26
			Mean	0.002	0.009	0.005
			95% CI	-0.001, 0.004	0.004, 0.013	0.003, 0.008
	SARS-CoV-2 S2	**Any Th2**	n	12	14	26
			Mean	0.012	0.021	0.017
			95% CI	0.003, 0.020	0.013, 0.029	0.011, 0.022
		IL-13	n	12	14	26
			Mean	0.008	0.016	0.012
			95% CI	0.002, 0.015	0.007, 0.024	0.007, 0.018

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
		IL-4	n	12	14	26
			Mean	0.003	0.008	0.006
			95% CI	-0.002, 0.008	0.005, 0.011	0.003, 0.009

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 55:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th2 Response – Age 56-70, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th2**	n	9	9	18
			Mean	0.001	0.000	0.001
			95% CI	-0.001, 0.004	NE	-0.001, 0.002
		IL-13	n	9	9	18
			Mean	0.001	0.001	0.001
			95% CI	-0.001, 0.004	-0.001, 0.004	0.000, 0.003
		IL-4	n	9	9	18
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	9	9	18
			Mean	0.001	0.001	0.001
			95% CI	-0.001, 0.004	-0.001, 0.004	0.000, 0.003
		IL-13	n	9	9	18
			Mean	0.001	0.001	0.001
			95% CI	-0.001, 0.004	-0.001, 0.004	0.000, 0.003
		IL-4	n	9	9	18
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	9	9	18
			Mean	0.000	0.002	0.001
			95% CI	NE	-0.001, 0.006	0.000, 0.003
		IL-13	n	9	9	18
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
		IL-4	n	9	9	18
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	9	9	18
			Mean	0.002	0.006	0.004
			95% CI	-0.001, 0.006	0.002, 0.010	0.001, 0.006
		IL-13	n	9	9	18
			Mean	0.001	0.002	0.002
			95% CI	-0.001, 0.004	-0.001, 0.006	0.000, 0.004
		IL-4	n	9	9	18
			Mean	0.000	0.003	0.002
			95% CI	NE	-0.001, 0.007	0.000, 0.004
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	9	8	17
			Mean	0.022	0.029	0.025
			95% CI	0.012, 0.033	0.010, 0.047	0.016, 0.035
		IL-13	n	9	8	17
			Mean	0.019	0.018	0.018
			95% CI	0.007, 0.031	0.005, 0.030	0.011, 0.026
		IL-4	n	9	8	17
			Mean	0.010	0.021	0.015
			95% CI	0.006, 0.014	0.008, 0.035	0.009, 0.022
	SARS-CoV-2 S2	**Any Th2**	n	9	8	17
			Mean	0.021	0.035	0.028
			95% CI	0.011, 0.032	0.007, 0.063	0.015, 0.041
		IL-13	n	9	8	17
			Mean	0.016	0.024	0.019
			95% CI	0.005, 0.026	0.000, 0.047	0.008, 0.030

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
		IL-4	n	9	8	17
			Mean	0.011	0.020	0.015
			95% CI	0.006, 0.016	0.002, 0.038	0.007, 0.023

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 56:
Mean Percentages of CD4 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - - Th2 Response – Age ≥71, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any Th2**	n	10	10	20
			Mean	0.009	0.002	0.006
			95% CI	-0.007, 0.025	-0.001, 0.005	-0.002, 0.013
		IL-13	n	10	10	20
			Mean	0.009	0.002	0.006
			95% CI	-0.007, 0.025	-0.001, 0.005	-0.002, 0.013
		IL-4	n	10	10	20
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	10	10	20
			Mean	0.010	0.004	0.007
			95% CI	-0.010, 0.030	0.000, 0.008	-0.002, 0.016
		IL-13	n	10	10	20
			Mean	0.011	0.004	0.008
			95% CI	-0.009, 0.031	0.000, 0.008	-0.002, 0.017
		IL-4	n	10	10	20
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	10	10	20
			Mean	0.012	0.002	0.007
			95% CI	-0.008, 0.032	-0.001, 0.005	-0.002, 0.016
		IL-13	n	10	10	20
			Mean	0.011	0.002	0.007
			95% CI	-0.009, 0.031	-0.001, 0.005	-0.003, 0.016

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
		IL-4	n	10	10	20
			Mean	0.000	0.000	0.000
			95% CI	NE	NE	NE
	SARS-CoV-2 S2	**Any Th2**	n	10	10	20
			Mean	0.008	0.000	0.004
			95% CI	-0.008, 0.024	NE	-0.004, 0.012
		IL-13	n	10	10	20
			Mean	0.007	0.000	0.004
			95% CI	-0.009, 0.023	NE	-0.004, 0.011
		IL-4	n	10	10	20
			Mean	0.001	0.000	0.001
			95% CI	-0.001, 0.003	NE	-0.001, 0.002
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any Th2**	n	10	10	20
			Mean	0.015	0.023	0.019
			95% CI	0.009, 0.021	0.011, 0.035	0.013, 0.025
		IL-13	n	10	10	20
			Mean	0.013	0.015	0.014
			95% CI	0.007, 0.019	0.008, 0.022	0.010, 0.018
		IL-4	n	10	10	20
			Mean	0.005	0.015	0.010
			95% CI	0.001, 0.009	0.007, 0.023	0.005, 0.015
	SARS-CoV-2 S2	**Any Th2**	n	10	10	20
			Mean	0.020	0.027	0.024
			95% CI	0.008, 0.032	0.016, 0.038	0.016, 0.031
		IL-13	n	10	10	20
			Mean	0.017	0.017	0.017
			95% CI	0.004, 0.030	0.007, 0.027	0.010, 0.024

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
		IL-4	n	10	10	20
			Mean	0.005	0.016	0.011
			95% CI	0.001, 0.009	0.008, 0.024	0.006, 0.015

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 57:
Mean Percentages of CD8 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - Age 18-55, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any CD8**	n	15	15	30
			Mean	0.008	0.002	0.005
			95% CI	-0.006, 0.022	-0.006, 0.010	-0.003, 0.013
		IFNγ	n	15	15	30
			Mean	0.002	-0.002	0.000
			95% CI	-0.006, 0.010	-0.008, 0.004	-0.005, 0.005
		IL-2	n	15	15	30
			Mean	0.003	0.003	0.003
			95% CI	-0.002, 0.008	0.000, 0.007	0.001, 0.006
		TNF	n	15	15	30
			Mean	0.007	0.001	0.004
			95% CI	-0.006, 0.021	-0.006, 0.007	-0.003, 0.011
	SARS-CoV-2 S2	**Any CD8**	n	15	15	30
			Mean	-0.002	-0.003	-0.002
			95% CI	-0.011, 0.007	-0.015, 0.009	-0.009, 0.005
		IFNγ	n	15	15	30
			Mean	0.001	-0.002	-0.001
			95% CI	-0.003, 0.005	-0.006, 0.002	-0.003, 0.002
		IL-2	n	15	15	30
			Mean	-0.003	-0.001	-0.002
			95% CI	-0.008, 0.003	-0.009, 0.007	-0.006, 0.003
		TNF	n	15	15	30
			Mean	0.003	0.000	0.001
			95% CI	-0.004, 0.009	-0.006, 0.006	-0.003, 0.005

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	14	15	29
			Mean	0.008	0.010	0.009
			95% CI	0.000, 0.016	-0.002, 0.022	0.002, 0.016
		IFNγ	n	14	15	29
			Mean	0.001	0.006	0.003
			95% CI	-0.004, 0.005	0.000, 0.012	0.000, 0.007
		IL-2	n	14	15	29
			Mean	0.004	0.002	0.003
			95% CI	-0.001, 0.010	-0.009, 0.013	-0.003, 0.009
		TNF	n	14	15	29
			Mean	0.001	0.008	0.004
			95% CI	-0.005, 0.007	0.002, 0.014	0.000, 0.009
	SARS-CoV-2 S2	**Any CD8**	n	14	15	29
			Mean	0.004	0.005	0.005
			95% CI	-0.006, 0.014	-0.007, 0.018	-0.003, 0.012
		IFNγ	n	14	15	29
			Mean	0.003	0.004	0.003
			95% CI	-0.003, 0.009	-0.002, 0.010	0.000, 0.007
		IL-2	n	14	15	29
			Mean	0.004	-0.001	0.002
			95% CI	-0.003, 0.012	-0.012, 0.011	-0.005, 0.008
		TNF	n	14	15	29
			Mean	0.004	0.007	0.006
			95% CI	-0.002, 0.009	0.001, 0.014	0.002, 0.010
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	12	14	26
			Mean	0.028	0.046	0.037
			95% CI	0.006, 0.049	0.013, 0.078	0.018, 0.056

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=45)
		IFNγ	n	12	14	26
			Mean	0.019	0.046	0.033
			95% CI	-0.003, 0.041	0.016, 0.076	0.015, 0.052
		IL-2	n	12	14	26
			Mean	0.017	0.018	0.017
			95% CI	0.003, 0.030	0.001, 0.035	0.007, 0.028
		TNF	n	12	14	26
			Mean	0.018	0.026	0.022
			95% CI	-0.001, 0.038	0.005, 0.046	0.009, 0.036
	SARS-CoV-2 S2	**Any CD8**	n	12	14	26
			Mean	0.018	0.021	0.020
			95% CI	0.004, 0.033	0.009, 0.034	0.011, 0.029
		IFNγ	n	12	14	26
			Mean	0.017	0.018	0.017
			95% CI	0.005, 0.028	0.011, 0.025	0.011, 0.023
		IL-2	n	12	14	26
			Mean	0.008	0.011	0.010
			95% CI	-0.001, 0.017	0.004, 0.018	0.004, 0.015
		TNF	n	12	14	26
			Mean	0.013	0.011	0.012
			95% CI	0.000, 0.026	0.001, 0.020	0.005, 0.019

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 58:
Mean Percentages of CD8 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group – Age 56-70, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any CD8**	n	9	9	18
			Mean	-0.004	0.002	-0.001
			95% CI	-0.022, 0.013	-0.007, 0.011	-0.010, 0.008
		IFNγ	n	9	9	18
			Mean	-0.001	0.001	0.000
			95% CI	-0.007, 0.005	-0.005, 0.007	-0.004, 0.004
		IL-2	n	9	9	18
			Mean	-0.001	-0.001	-0.001
			95% CI	-0.006, 0.004	-0.007, 0.005	-0.004, 0.002
		TNF	n	9	9	18
			Mean	-0.003	0.000	-0.002
			95% CI	-0.019, 0.012	-0.007, 0.007	-0.009, 0.006
	SARS-CoV-2 S2	**Any CD8**	n	9	9	18
			Mean	0.010	0.002	0.006
			95% CI	-0.021, 0.041	-0.014, 0.018	-0.010, 0.022
		IFNγ	n	9	9	18
			Mean	0.012	0.000	0.006
			95% CI	-0.010, 0.034	-0.009, 0.009	-0.005, 0.017
		IL-2	n	9	9	18
			Mean	0.000	-0.001	-0.001
			95% CI	-0.008, 0.008	-0.008, 0.006	-0.005, 0.004
		TNF	n	9	9	18
			Mean	0.010	0.002	0.006
			95% CI	-0.016, 0.036	-0.007, 0.011	-0.006, 0.018

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	9	9	18
			Mean	-0.004	0.023	0.009
			95% CI	-0.023, 0.014	0.007, 0.039	-0.004, 0.022
		IFNγ	n	9	9	18
			Mean	-0.002	0.000	-0.001
			95% CI	-0.014, 0.009	-0.011, 0.011	-0.008, 0.006
		IL-2	n	9	9	18
			Mean	0.001	0.008	0.004
			95% CI	-0.001, 0.004	0.003, 0.013	0.001, 0.008
		TNF	n	9	9	18
			Mean	-0.008	0.017	0.004
			95% CI	-0.026, 0.010	0.001, 0.033	-0.008, 0.017
	SARS-CoV-2 S2	**Any CD8**	n	9	9	18
			Mean	0.003	0.003	0.003
			95% CI	-0.024, 0.031	-0.006, 0.013	-0.010, 0.016
		IFNγ	n	9	9	18
			Mean	0.004	0.002	0.003
			95% CI	-0.013, 0.022	-0.003, 0.007	-0.005, 0.011
		IL-2	n	9	9	18
			Mean	0.003	0.000	0.002
			95% CI	-0.001, 0.007	-0.008, 0.008	-0.002, 0.006
		TNF	n	9	9	18
			Mean	0.007	0.003	0.005
			95% CI	-0.020, 0.033	-0.004, 0.011	-0.007, 0.017
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	9	8	17
			Mean	0.089	0.075	0.082
			95% CI	-0.025, 0.202	0.031, 0.119	0.026, 0.139

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=20)
		IFNγ	n	9	8	17
			Mean	0.088	0.058	0.074
			95% CI	-0.020, 0.195	0.024, 0.091	0.020, 0.127
		IL-2	n	9	8	17
			Mean	0.047	0.029	0.038
			95% CI	-0.012, 0.105	0.003, 0.054	0.008, 0.068
		TNF	n	9	8	17
			Mean	0.061	0.036	0.049
			95% CI	-0.032, 0.154	0.002, 0.071	0.003, 0.096
	SARS-CoV-2 S2	**Any CD8**	n	9	8	17
			Mean	0.264	0.026	0.152
			95% CI	-0.080, 0.608	0.006, 0.047	-0.022, 0.327
		IFNγ	n	9	8	17
			Mean	0.254	0.021	0.145
			95% CI	-0.077, 0.586	0.001, 0.042	-0.024, 0.313
		IL-2	n	9	8	17
			Mean	0.122	0.009	0.069
			95% CI	-0.049, 0.293	-0.001, 0.018	-0.017, 0.155
		TNF	n	9	8	17
			Mean	0.204	0.016	0.116
			95% CI	-0.060, 0.469	-0.005, 0.037	-0.019, 0.251

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 59:
Mean Percentages of CD8 T cells expressing cytokines with 95% CI with 95% Confidence Intervals by Time Point and Treatment Group - Age ≥71, Per Protocol Population

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
Day 1 (Pre-Vaccination 1)	**SARS-CoV-2 S1**	**Any CD8**	n	10	10	20
			Mean	0.006	-0.005	0.001
			95% CI	-0.005, 0.017	-0.024, 0.014	-0.010, 0.011
		IFNγ	n	10	10	20
			Mean	0.003	-0.008	-0.003
			95% CI	-0.007, 0.013	-0.020, 0.004	-0.010, 0.005
		IL-2	n	10	10	20
			Mean	-0.002	-0.003	-0.003
			95% CI	-0.007, 0.003	-0.010, 0.004	-0.006, 0.001
		TNF	n	10	10	20
			Mean	0.004	-0.002	0.001
			95% CI	-0.007, 0.015	-0.021, 0.017	-0.009, 0.011
	SARS-CoV-2 S2	**Any CD8**	n	10	10	20
			Mean	0.009	0.043	0.026
			95% CI	-0.002, 0.020	-0.028, 0.114	-0.007, 0.059
		IFNγ	n	10	10	20
			Mean	0.002	0.034	0.018
			95% CI	-0.009, 0.013	-0.031, 0.099	-0.013, 0.049
		IL-2	n	10	10	20
			Mean	0.001	0.025	0.013
			95% CI	-0.005, 0.007	-0.014, 0.064	-0.006, 0.032
		TNF	n	10	10	20
			Mean	0.008	0.044	0.026
			95% CI	0.000, 0.016	-0.023, 0.111	-0.006, 0.058

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	10	10	20
			Mean	-0.009	-0.010	-0.010
			95% CI	-0.029, 0.011	-0.030, 0.010	-0.022, 0.003
		IFNγ	n	10	10	20
			Mean	0.002	-0.007	-0.003
			95% CI	-0.013, 0.017	-0.021, 0.007	-0.012, 0.007
		IL-2	n	10	10	20
			Mean	-0.006	0.001	-0.003
			95% CI	-0.015, 0.003	-0.008, 0.010	-0.009, 0.004
		TNF	n	10	10	20
			Mean	-0.011	-0.004	-0.008
			95% CI	-0.029, 0.007	-0.022, 0.014	-0.019, 0.004
	SARS-CoV-2 S2	**Any CD8**	n	10	10	20
			Mean	0.015	-0.005	0.005
			95% CI	-0.018, 0.048	-0.030, 0.020	-0.014, 0.024
		IFNγ	n	10	10	20
			Mean	0.022	-0.005	0.009
			95% CI	0.000, 0.044	-0.025, 0.015	-0.007, 0.024
		IL-2	n	10	10	20
			Mean	0.002	0.001	0.002
			95% CI	-0.009, 0.013	-0.008, 0.010	-0.005, 0.008
		TNF	n	10	10	20
			Mean	0.004	0.002	0.003
			95% CI	-0.029, 0.037	-0.020, 0.024	-0.015, 0.021
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	**SARS-CoV-2 S1**	**Any CD8**	n	10	10	20
			Mean	0.035	0.128	0.082
			95% CI	0.005, 0.065	-0.014, 0.270	0.013, 0.150

Time Point	Simulation	Cell Type	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=20)
		IFNγ	n	10	10	20
			Mean	0.031	0.126	0.079
			95% CI	0.007, 0.055	-0.012, 0.264	0.011, 0.146
		IL-2	n	10	10	20
			Mean	0.008	0.056	0.032
			95% CI	-0.001, 0.017	-0.001, 0.113	0.004, 0.060
		TNF	n	10	10	20
			Mean	0.018	0.087	0.053
			95% CI	0.005, 0.031	-0.018, 0.192	0.002, 0.103
	SARS-CoV-2 S2	**Any CD8**	n	10	10	20
			Mean	0.050	0.022	0.036
			95% CI	0.003, 0.097	-0.004, 0.048	0.011, 0.061
		IFNγ	n	10	10	20
			Mean	0.042	0.021	0.032
			95% CI	-0.007, 0.091	-0.004, 0.046	0.006, 0.057
		IL-2	n	10	10	20
			Mean	0.028	0.011	0.020
			95% CI	0.003, 0.053	0.000, 0.022	0.006, 0.033
		TNF	n	10	10	20
			Mean	0.034	0.021	0.028
			95% CI	0.013, 0.055	0.005, 0.037	0.015, 0.040

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 60:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group – S-2P – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60
	GMFR[a]	278.9	197.4	656.6	915.8	426.5
	95% CI	120.712, 644.309	94.925, 410.543	327.061, 1318.056	418.821, 2002.329	290.797, 625.661
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	60/60 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	78.2%, 100%	94%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59
	GMFR[a]	347.7	346.5	831	1259.5	588.4
	95% CI	170.898, 707.61	134.007, 895.728	379.435, 1819.776	533.04, 2975.799	392.847, 881.246
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	59/59 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.9%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	2971	2538.1	5945.5	7443.6	4287.1
	95% CI	1440.586, 6127.2	860.349, 7487.837	2824.739, 12514.226	3258.379, 17004.433	2842.637, 6465.518
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	57/57 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.7%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55
	GMFR[a]	2885.5	2609.5	6381.4	5866.7	4123.7
	95% CI	1489.891, 5588.303	1052.283, 6471.24	2845.746, 14310.027	2489.211, 13826.839	2805.55, 6061.279
	4-Fold Rise[b]	13/13 (100%)	14/14 (100%)	14/14 (100%)	14/14 (100%)	55/55 (100%)
	95% CI	75.3%, 100%	76.8%, 100%	76.8%, 100%	76.8%, 100%	93.5%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56
	GMFR[a]	2277.5	1646.2	6158	7404.7	3595
	95% CI	1061.856, 4884.982	691.442, 3919.159	3200.137, 11849.779	2850.706, 19233.461	2385.725, 5417.337

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	14/14 (100%)	14/14 (100%)	56/56 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	76.8%, 100%	76.8%, 100%	93.6%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42
	GMFR[a]	2291.1		3149.8	3565.6	2974.7
	95% CI	1210.086, 4337.908		1628.983, 6090.592	1347.745, 9433.154	1970.928, 4489.774
	4-Fold Rise[b]	13/13 (100%)		15/15 (100%)	14/14 (100%)	42/42 (100%)
	95% CI	75.3%, 100%		78.2%, 100%	76.8%, 100%	91.6%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 61:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group – S-2P – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	55.7	78.1	84.7	71.7
	95% CI	9.591, 323.362	39.516, 154.316	33.769, 212.561	38.792, 132.487
	4-Fold Rise[b]	9/10 (90%)	10/10 (100%)	10/10 (100%)	29/30 (96.7%)
	95% CI	55.5%, 99.7%	69.2%, 100%	69.2%, 100%	82.8%, 99.9%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	93.7	79.7	176.7	109.7
	95% CI	16.087, 545.965	35.91, 176.774	61.08, 511.281	56.984, 211.117
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	1662.5	358.6	7919.9	1590.2
	95% CI	445.872, 6199.194	157.078, 818.701	960.785, 65284.929	663.046, 3813.998
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	2523.3	745.3	2055.1	1554.8
	95% CI	856.026, 7437.66	390.824, 1421.134	391.227, 10795.348	839.174, 2880.524
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	1716.7	559.3	1861.7	1195.8
	95% CI	428.352, 6880.259	319.822, 978.087	306.421, 11310.5	599.411, 2385.743

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19
	GMFR[a]	457.8		576.3	510.6
	95% CI	131.067, 1599.219		173.445, 1915.046	233.761, 1115.163
	4-Fold Rise[b]	10/10 (100%)		9/9 (100%)	19/19 (100%)
	95% CI	69.2%, 100%		66.4%, 100%	82.4%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 62:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Vaccination Group – S-2P – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	133.7	20.7	110	67.3
	95% CI	54.367, 328.996	6.406, 66.923	31.725, 381.607	35.284, 128.329
	4-Fold Rise[b]	10/10 (100%)	9/10 (90%)	10/10 (100%)	29/30 (96.7%)
	95% CI	69.2%, 100%	55.5%, 99.7%	69.2%, 100%	82.8%, 99.9%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	522.7	49.9	213.3	177.2
	95% CI	177.45, 1539.595	15.523, 160.463	102.234, 444.994	94.529, 332.171
	4-Fold Rise[b]	10/10 (100%)	9/10 (90%)	10/10 (100%)	29/30 (96.7%)
	95% CI	69.2%, 100%	55.5%, 99.7%	69.2%, 100%	82.8%, 99.9%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	4147.3	297.6	2765.7	1505.6
	95% CI	1610.973, 10676.865	97.451, 908.669	796.806, 9599.661	739.531, 3065.403
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	2736.9	774.8	8486.4	2620.6
	95% CI	913.801, 8197.41	213.685, 2809.551	2252.854, 31967.873	1266.553, 5422.157
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	10171.4	483.8	3816.1	2658
	95% CI	3722.344, 27793.388	164.278, 1424.865	1263.313, 11527.479	1292.484, 5466.303

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20
	GMFR[a]	682.2		204.8	373.8
	95% CI	271.77, 1712.245		103.019, 407.152	206.704, 675.884
	4-Fold Rise[b]	10/10 (100%)		10/10 (100%)	20/20 (100%)
	95% CI	69.2%, 100%		69.2%, 100%	83.2%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 63:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - RBD – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60
	GMFR[a]	118.2	46.4	205.2	152	114.4
	95% CI	60.898, 229.597	24.51, 87.967	105.889, 397.681	74.295, 310.933	81.634, 160.303
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	60/60 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	78.2%, 100%	94%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59
	GMFR[a]	326.8	113.3	561.5	222.1	261.4
	95% CI	194.534, 549.007	51.602, 248.935	264.941, 1189.944	107.021, 461.001	183.349, 372.712
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	59/59 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.9%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	3696.8	1122.4	3008.5	1333.4	1991.9
	95% CI	2273.806, 6010.434	669.718, 1881.009	1610.699, 5619.25	768.976, 2312.173	1499.044, 2646.88
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	57/57 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.7%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55
	GMFR[a]	4132.9	1073.8	3527.7	1191.9	2052.6
	95% CI	2714.982, 6291.356	726.77, 1586.535	1637.818, 7598.401	640.566, 2217.76	1508.041, 2793.749
	4-Fold Rise[b]	13/13 (100%)	14/14 (100%)	14/14 (100%)	14/14 (100%)	55/55 (100%)
	95% CI	75.3%, 100%	76.8%, 100%	76.8%, 100%	76.8%, 100%	93.5%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56
	GMFR[a]	3253.9	877.3	2343.4	1043.6	1587.9
	95% CI	1989.818, 5320.999	557.835, 1379.568	963.92, 5697.1	494.474, 2202.725	1135.132, 2221.189

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	14/14 (100%)	14/14 (100%)	56/56 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	76.8%, 100%	76.8%, 100%	93.6%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42
	GMFR[a]	2497.9		1416.7	415.5	1121.9
	95% CI	1363.387, 4576.607		685.114, 2929.333	209.466, 824.301	731.156, 1721.439
	4-Fold Rise[b]	13/13 (100%)		15/15 (100%)	14/14 (100%)	42/42 (100%)
	95% CI	75.3%, 100%		78.2%, 100%	76.8%, 100%	91.6%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 64:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Vaccination Group - RBD – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	14.4	24.1	138.9	36.4
	95% CI	2.731, 75.518	12.171, 47.635	47.299, 407.876	17.842, 74.059
	4-Fold Rise[b]	6/10 (60%)	10/10 (100%)	10/10 (100%)	26/30 (86.7%)
	95% CI	26.2%, 87.8%	69.2%, 100%	69.2%, 100%	69.3%, 96.2%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	23.8	39	204.8	57.5
	95% CI	5.815, 97.222	19.878, 76.362	54.657, 767.682	28.825, 114.556
	4-Fold Rise[b]	8/10 (80%)	10/10 (100%)	9/10 (90%)	27/30 (90%)
	95% CI	44.4%, 97.5%	69.2%, 100%	55.5%, 99.7%	73.5%, 97.9%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	975.7	303.4	5588.7	1121.1
	95% CI	330.172, 2883.052	136.067, 676.699	2486.983, 12558.802	586.253, 2143.832
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	989.7	701.8	3818.4	1336.6
	95% CI	411.217, 2381.821	272.086, 1809.923	2065.08, 7060.283	806.259, 2215.649
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	383.3	578.1	1922.6	728.5
	95% CI	156.909, 936.467	249.122, 1341.482	379.042, 9752.418	390.374, 1359.569

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19
	GMFR[a]	223.1		576.2	349.7
	95% CI	82.895, 600.403		168.76, 1967.559	167.59, 729.704
	4-Fold Rise[b]	10/10 (100%)		9/9 (100%)	19/19 (100%)
	95% CI	69.2%, 100%		66.4%, 100%	82.4%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 65:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - RBD - Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	42	11	51	28.7
	95% CI	14.344, 123.269	2.664, 45.538	17.028, 152.836	14.816, 55.577
	4-Fold Rise[b]	9/10 (90%)	6/10 (60%)	9/10 (90%)	24/30 (80%)
	95% CI	55.5%, 99.7%	26.2%, 87.8%	55.5%, 99.7%	61.4%, 92.3%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	137.9	42.5	112	86.9
	95% CI	37.219, 511.138	11.334, 159.667	39.4, 318.233	45.361, 166.61
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	1444.1	407.4	1414.5	940.6
	95% CI	386.702, 5392.916	109.903, 1510.464	487.842, 4101.419	485.178, 1823.658
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	2654.5	657	1380.2	1340.2
	95% CI	760.064, 9270.938	173.077, 2494.327	475.685, 4004.465	697.978, 2573.364
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	1962.8	626.3	901.3	1034.8
	95% CI	480.831, 8012.1	180.418, 2174.381	270.671, 3001.108	527.738, 2028.964

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20
	GMFR[a]	593.4		313.9	431.6
	95% CI	150.964, 2332.394		88.358, 1115.129	183.754, 1013.644
	4-Fold Rise[b]	10/10 (100%)		10/10 (100%)	20/20 (100%)
	95% CI	69.2%, 100%		69.2%, 100%	83.2%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in titre compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in titre compared to pre-dose 1

TABLE 66:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - S-2P – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60
	GMFR[a]	13517.3	2876.2	28300.6	39579.8	14445.8
	95% CI	4705.476, 38830.697	783.075, 10563.891	8319.721, 96267.799	11551.751, 135612.504	7864.232, 26535.639
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	60/60 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	78.2%, 100%	94%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59
	GMFR[a]	19786.2	4048.9	30463	53290.8	18661.1
	95% CI	7164.525, 54643.201	957.412, 17122.958	9185.964, 101023.082	14486.651, 196036.104	10042.396, 34676.463
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	59/59 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.9%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	197551.8	36425.6	316250.4	437609.9	174206.2
	95% CI	76518.696, 510028.44	7798.346, 170141.319	95307.907, 1049380.846	116316.547, 1646389.964	91812.04, 330542.815
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	57/57 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.7%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55
	GMFR[a]	189426.3	49759.1	348444.2	352576.7	184380.7
	95% CI	73319.816, 489394.379	12225.925, 202517.648	104253.422, 1164598.06	89054.744, 1395886.778	100441.111, 338469.387
	4-Fold Rise[b]	13/13 (100%)	14/14 (100%)	14/14 (100%)	14/14 (100%)	55/55 (100%)
	95% CI	75.3%, 100%	76.8%, 100%	76.8%, 100%	76.8%, 100%	93.5%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56
	GMFR[a]	162021.8	27067.3	231292.3	301901.8	128125
	95% CI	65611.312, 400099.793	6418.715, 114140.817	71428.076, 748950.815	72359.981, 1259601.233	68057.78, 241207.102

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	14/14 (100%)	14/14 (100%)	56/56 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	76.8%, 100%	76.8%, 100%	93.6%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42
	GMFR[a]	88363.1		120772.9	123153.4	110355.3
	95% CI	37510.935, 208153.648		38894.992, 375012.131	30463.478, 497866.665	59654.813, 204145.977
	4-Fold Rise[b]	13/13 (100%)		15/15 (100%)	14/14 (100%)	42/42 (100%)
	95% CI	75.3%, 100%		78.2%, 100%	76.8%, 100%	91.6%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

TABLE 67:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - S-2P – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	646.1	577.2	1554.2	833.7
	95% CI	60.428, 6908.027	208.511, 1597.533	294.228, 8209.33	336.185, 2067.639
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	1901.4	639.1	3242.6	1579.5
	95% CI	254.995, 14177.838	229.702, 1778.131	510.697, 20588.28	651.345, 3830.068
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	42875.4	3081.7	201812	27970.8
	95% CI	9113.733, 201706.45	1034.776, 9177.489	11404.31, 3571288.573	8765.993, 89250.256
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	60321.7	7286	52374.3	27853.9
	95% CI	13316.359, 273250.697	2379.815, 22306.921	4541.146, 604048.204	10890.6, 71239.625
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	46727.4	6614	50193	24345.5
	95% CI	9097.671, 240000.904	2415.043, 18113.736	3790.03, 664726.375	9249.316, 64081.009

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19
	GMFR[a]	15538.9		11733.9	13603.2
	95% CI	3376.496, 71511.032		1533.426, 89789.288	4432.543, 41747.468
	4-Fold Rise[b]	10/10 (100%)		9/9 (100%)	19/19 (100%)
	95% CI	69.2%, 100%		66.4%, 100%	82.4%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

TABLE 68:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - S-2P – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	2675.4	195.8	1099.6	832
	95% CI	703.62, 10172.812	36.077, 1062.215	276.216, 4377.487	355.27, 1948.376
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	9566.4	619.7	1627.2	2128.8
	95% CI	1889.759, 48427.363	106.352, 3611.298	674.532, 3925.353	902.747, 5019.917
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	153704.3	4816.8	37906.4	30389.1
	95% CI	32850.917, 719158.116	827.715, 28030.652	8871.888, 161960.176	11562.54, 79869.971
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	113582.3	14583.4	86577.5	52343
	95% CI	22921.287, 562836.24	1979.471, 107441.31	17699.503, 423496.07	20415.194, 134203.499
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	229435.8	12102.9	35602.9	46239.4
	95% CI	44400.689, 1185585.328	1786.003, 82016.051	9408.664, 134723.639	17901.765, 119434.343

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20
	GMFR[a]	30055.9		3275.3	9921.7
	95% CI	6099.06, 148113.781		1284.014, 8354.491	3692.908, 26656.653
	4-Fold Rise[b]	10/10 (100%)		10/10 (100%)	20/20 (100%)
	95% CI	69.2%, 100%		69.2%, 100%	83.2%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

TABLE 69:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - RBD – Age 18-55, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
Day 15 (14 Days Post Vaccination 1)	n	15	15	15	15	60
	GMFR[a]	3303	527.8	6446.6	1227.7	1927.3
	95% CI	1407.253, 7752.747	214.752, 1297.039	2392.284, 17371.725	428.962, 3513.952	1170.438, 3173.575
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	60/60 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	78.2%, 100%	94%, 100%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59
	GMFR[a]	11712.5	1073.8	13861.2	1530.8	4108.8
	95% CI	6299.847, 21775.67	457.196, 2521.868	5106.887, 37622.531	521.232, 4495.926	2470.808, 6832.809
	4-Fold Rise[b]	15/15 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	59/59 (100%)
	95% CI	78.2%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.9%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	242797.8	12186.6	144272.7	17495.1	50494.7
	95% CI	167055.334, 352881.711	6675.661, 22246.954	57782.398, 360224.231	5949.763, 51443.577	30607.609, 83303.211
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	15/15 (100%)	14/14 (100%)	57/57 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	78.2%, 100%	76.8%, 100%	93.7%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55
	GMFR[a]	252840.4	14976	182400.6	14833.2	55055.9
	95% CI	164562.484, 388474.008	8439.084, 26576.497	63232.542, 526152.966	5002.234, 43985.075	32435.923, 93450.436
	4-Fold Rise[b]	13/13 (100%)	14/14 (100%)	14/14 (100%)	14/14 (100%)	55/55 (100%)
	95% CI	75.3%, 100%	76.8%, 100%	76.8%, 100%	76.8%, 100%	93.5%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	13	15	14	14	56
	GMFR[a]	304079.9	9471.2	136753.2	9907.9	41775.8
	95% CI	196663.913, 470165.358	5167.895, 17357.688	38437.242, 486544.503	3214.987, 30534.211	23127.207, 75461.527

Time Point	Statistic	25 µg mRNA-1273 18-55 years (N=15)	50 µg mRNA-1273 18-55 years (N=15)	100 µg mRNA-1273 18-55 years (N=15)	250 µg mRNA-1273 18-55 years (N=15)	18-55 years (N=60)
	4-Fold Rise[b]	13/13 (100%)	15/15 (100%)	14/14 (100%)	14/14 (100%)	56/56 (100%)
	95% CI	75.3%, 100%	78.2%, 100%	76.8%, 100%	76.8%, 100%	93.6%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13		15	14	42
	GMFR[a]	142175.1		52458	3784.5	29732.8
	95% CI	79548.615, 254105.676		17308.628, 158986.983	1219.519, 11744.035	14604.921, 60530.402
	4-Fold Rise[b]	13/13 (100%)		15/15 (100%)	14/14 (100%)	42/42 (100%)
	95% CI	75.3%, 100%		78.2%, 100%	76.8%, 100%	91.6%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

TABLE 70:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - RBD – Age 56-70, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	89.5	195.1	2849.1	367.8
	95% CI	6.846, 1170.081	42.257, 901.162	533.109, 15226.08	117.043, 1155.856
	4-Fold Rise[b]	8/10 (80%)	10/10 (100%)	10/10 (100%)	28/30 (93.3%)
	95% CI	44.4%, 97.5%	69.2%, 100%	69.2%, 100%	77.9%, 99.2%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	347.8	385	7497.3	1001.2
	95% CI	37.101, 3259.692	93.031, 1592.975	1412.603, 39791.469	347.112, 2888.01
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	21294.4	4153	179249.6	23474.7
	95% CI	4211.05, 107681.108	995.916, 17318.269	46618.695, 689217.73	9097.09, 60575.656
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	28288.8	9989.7	147903.1	33012
	95% CI	6621.785, 120852.198	1677.624, 59485.631	45858.866, 477014.403	13833.348, 78780.012
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	16457.8	7874.1	65402.2	19585.5
	95% CI	4037.599, 67083.981	1433.14, 43263.202	14720.933, 290569.194	8428.564, 45510.743

Time Point	Statistic	25 µg mRNA-1273 56-70 years (N=10)	50 µg mRNA-1273 56-70 years (N=10)	100 µg mRNA-1273 56-70 years (N=10)	56-70 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	9/9 (100%)	29/29 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	66.4%, 100%	88.1%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		9	19
	GMFR[a]	6643.5		21716.1	11642.6
	95% CI	1526.9, 28905.311		4197.282, 112355.335	4181.509, 32416.721
	4-Fold Rise[b]	10/10 (100%)		9/9 (100%)	19/19 (100%)
	95% CI	69.2%, 100%		66.4%, 100%	82.4%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

TABLE 71:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group - RBD – Age ≥71, Per Protocol Population

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
Day 15 (14 Days Post Vaccination 1)	n	10	10	10	30
	GMFR[a]	626.5	44.3	688.3	267.3
	95% CI	94.036, 4174.46	4.798, 408.419	138.787, 3413.586	90.536, 788.984
	4-Fold Rise[b]	9/10 (90%)	8/10 (80%)	10/10 (100%)	27/30 (90%)
	95% CI	55.5%, 99.7%	44.4%, 97.5%	69.2%, 100%	73.5%, 97.9%
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30
	GMFR[a]	4659.7	379.7	1884	1493.8
	95% CI	554.772, 39137.681	49.209, 2929.205	359.621, 9870.316	517.686, 4310.176
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 36 Post Vaccination 1 (7 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	88208.5	7489.9	35161.6	28533.3
	95% CI	13191.21, 589843.201	1266.959, 44277.866	7357.378, 168040.734	10885.684, 74790.586
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	95709.6	16616.4	25600.5	34401.7
	95% CI	14085.922, 650318.174	2736.074, 100912.603	5177.369, 126586.998	13452.348, 87975.711
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 57 Post Vaccination 1 (28 Days Post Vaccination 2)	n	10	10	10	30
	GMFR[a]	82718.3	13381.2	21960.5	28967.6
	95% CI	11765.849, 581540.787	2229.93, 80296.828	4231.851, 113960.787	11172.458, 75106.502

Time Point	Statistic	25 µg mRNA-1273 ≥71 years (N=10)	50 µg mRNA-1273 ≥71 years (N=10)	100 µg mRNA-1273 ≥71 years (N=10)	≥71 years (N=30)
	4-Fold Rise[b]	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
	95% CI	69.2%, 100%	69.2%, 100%	69.2%, 100%	88.4%, 100%
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10		10	20
	GMFR[a]	21900.8		6808.6	12211.2
	95% CI	3161.376, 151719.789		1190.524, 38938.675	3655.465, 40792.118
	4-Fold Rise[b]	10/10 (100%)		10/10 (100%)	20/20 (100%)
	95% CI	69.2%, 100%		69.2%, 100%	83.2%, 100%

Note: N=Number of Subjects.
Note: n=number of subjects with baseline and data at corresponding visit.
[a]GMFR represents the geometric mean fold rise in AUC compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in AUC compared to pre-dose 1
AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations.

Figure 4: Reverse Cumulative Distribution of Serum IgG Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

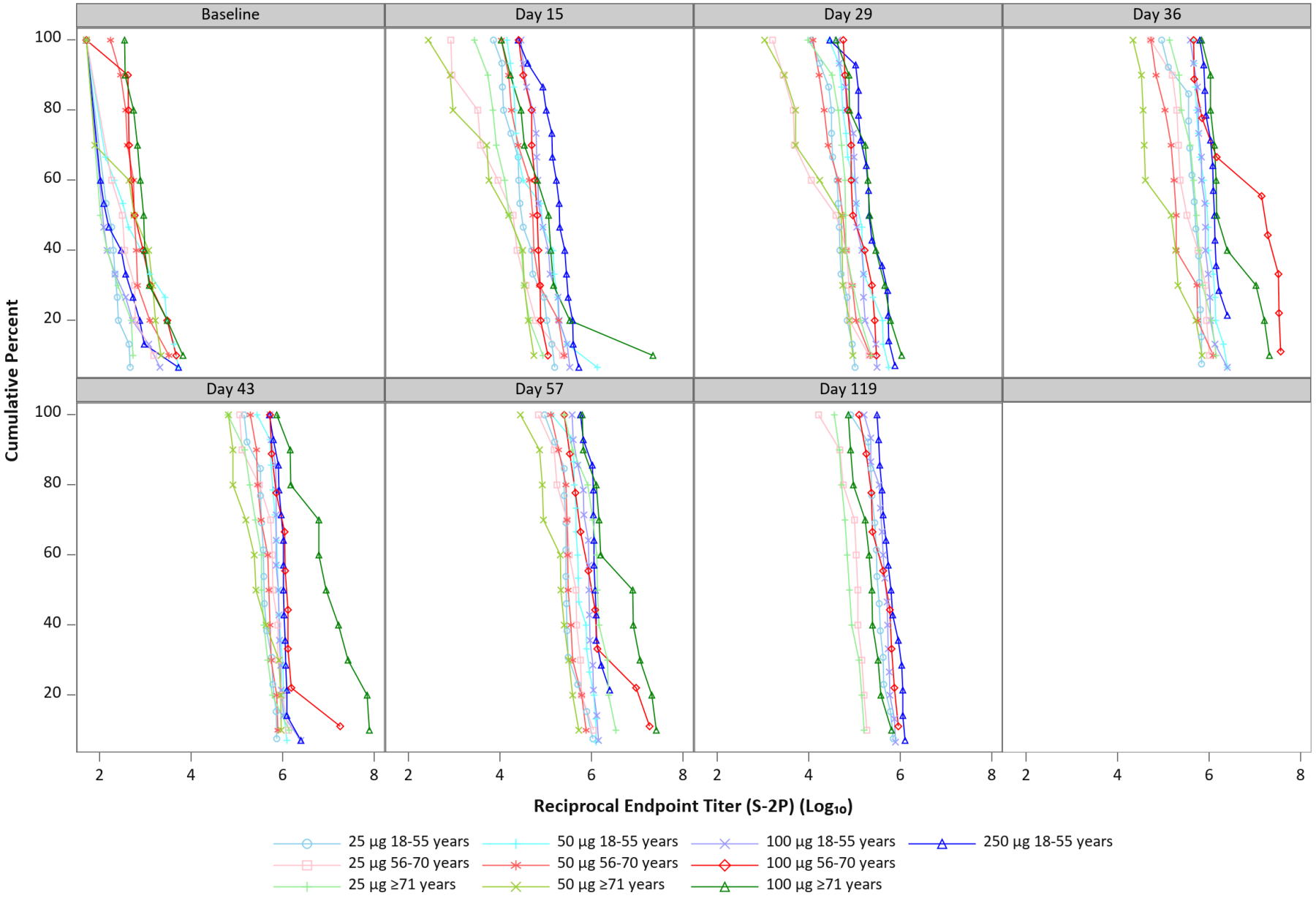


Figure 5: Reverse Cumulative Distribution of Serum IgG Endpoint Titer Values by Time Point and Treatment Group - RBD, Per Protocol Population

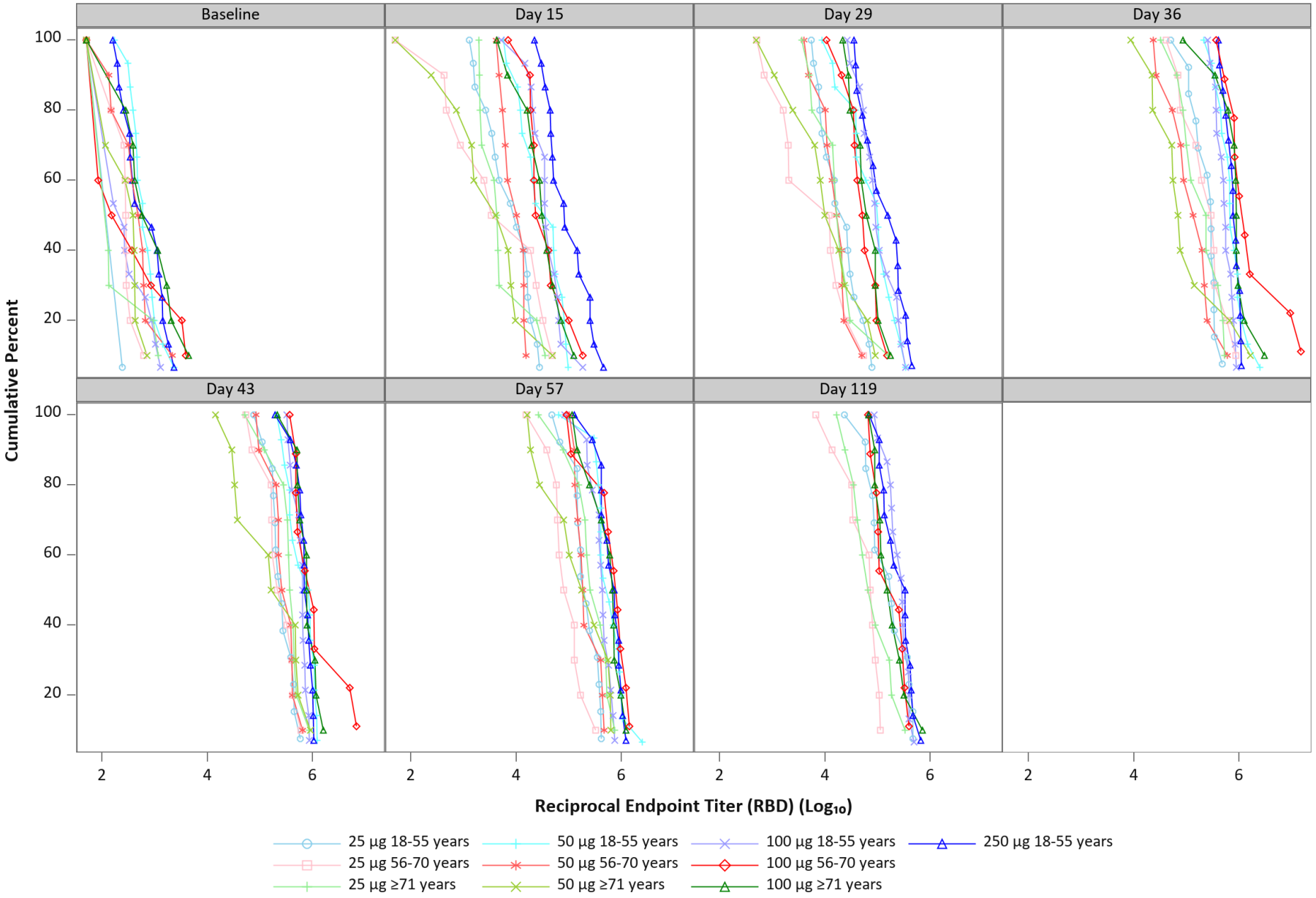


Figure 6: Reverse Cumulative Distribution of Serum IgG Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

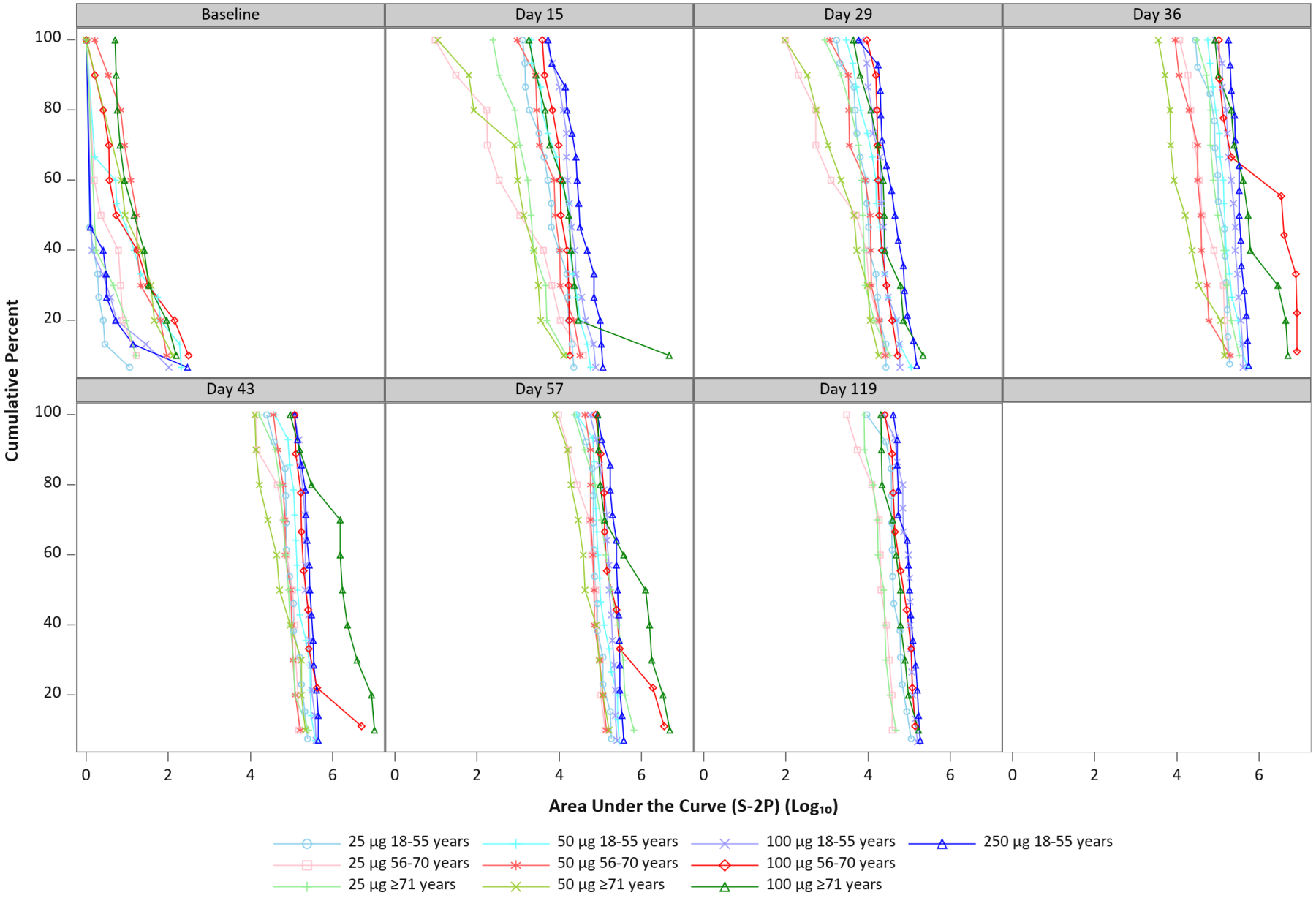


Figure 7: Reverse Cumulative Distribution of Serum IgG Area Under the Curve (AUC) Values by Time Point and Treatment Group - RBD, Per Protocol Population

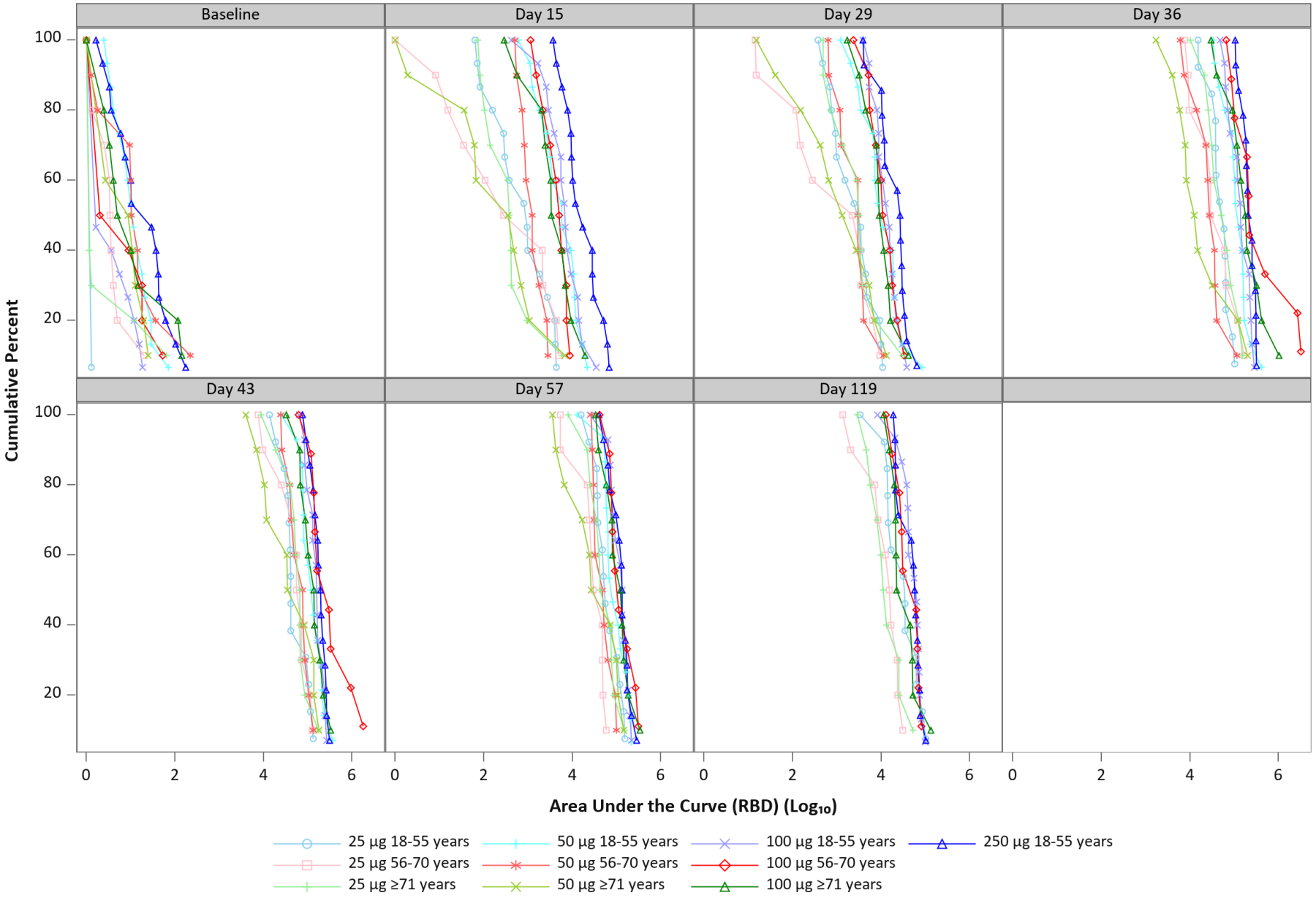


Figure 8: Serum IgG ELISA Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

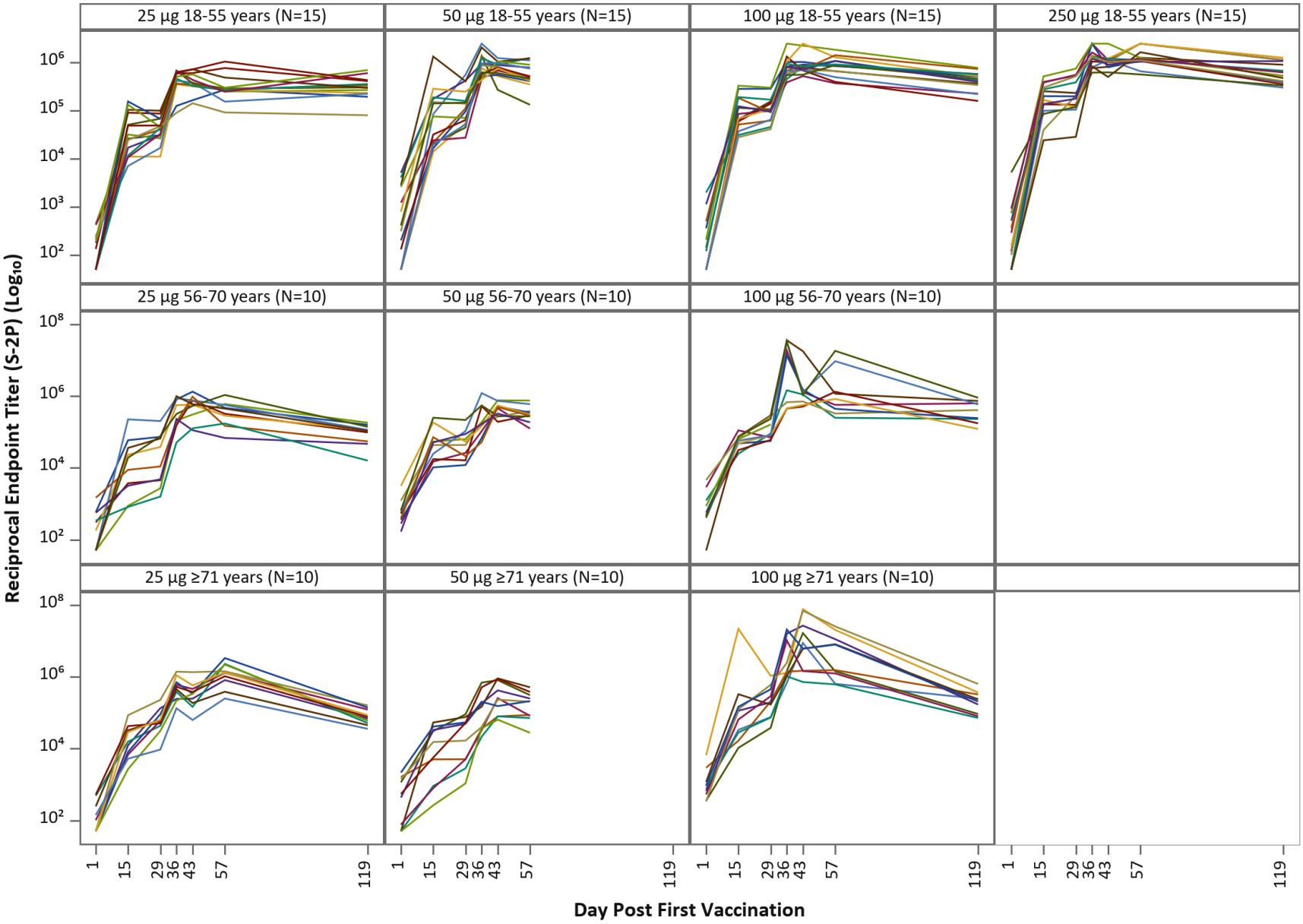


Figure 9: Serum IgG ELISA Endpoint Titer Values by Time Point and Treatment Group – RBD, Per Protocol Population

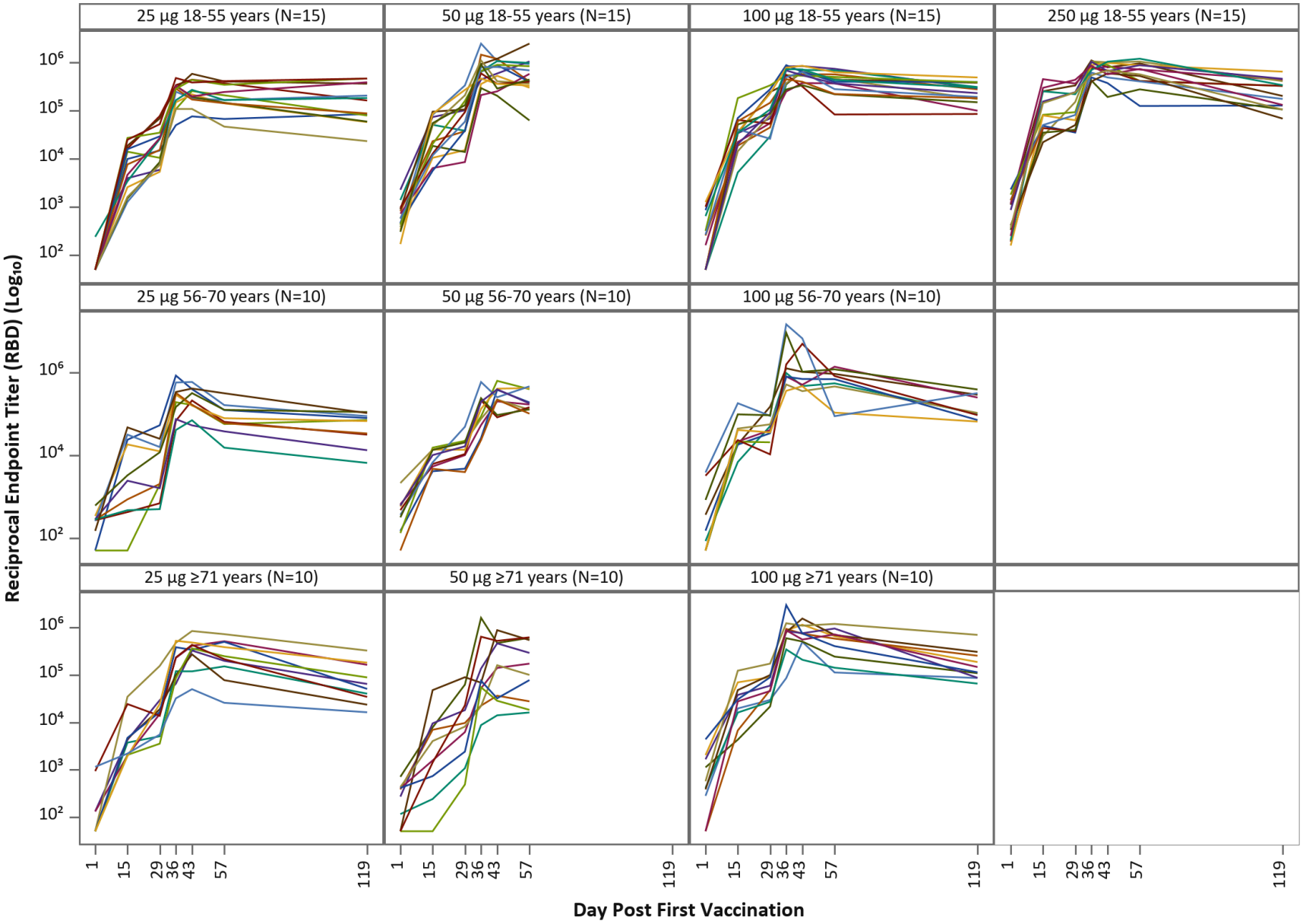


Figure 10: Serum IgG ELISA Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

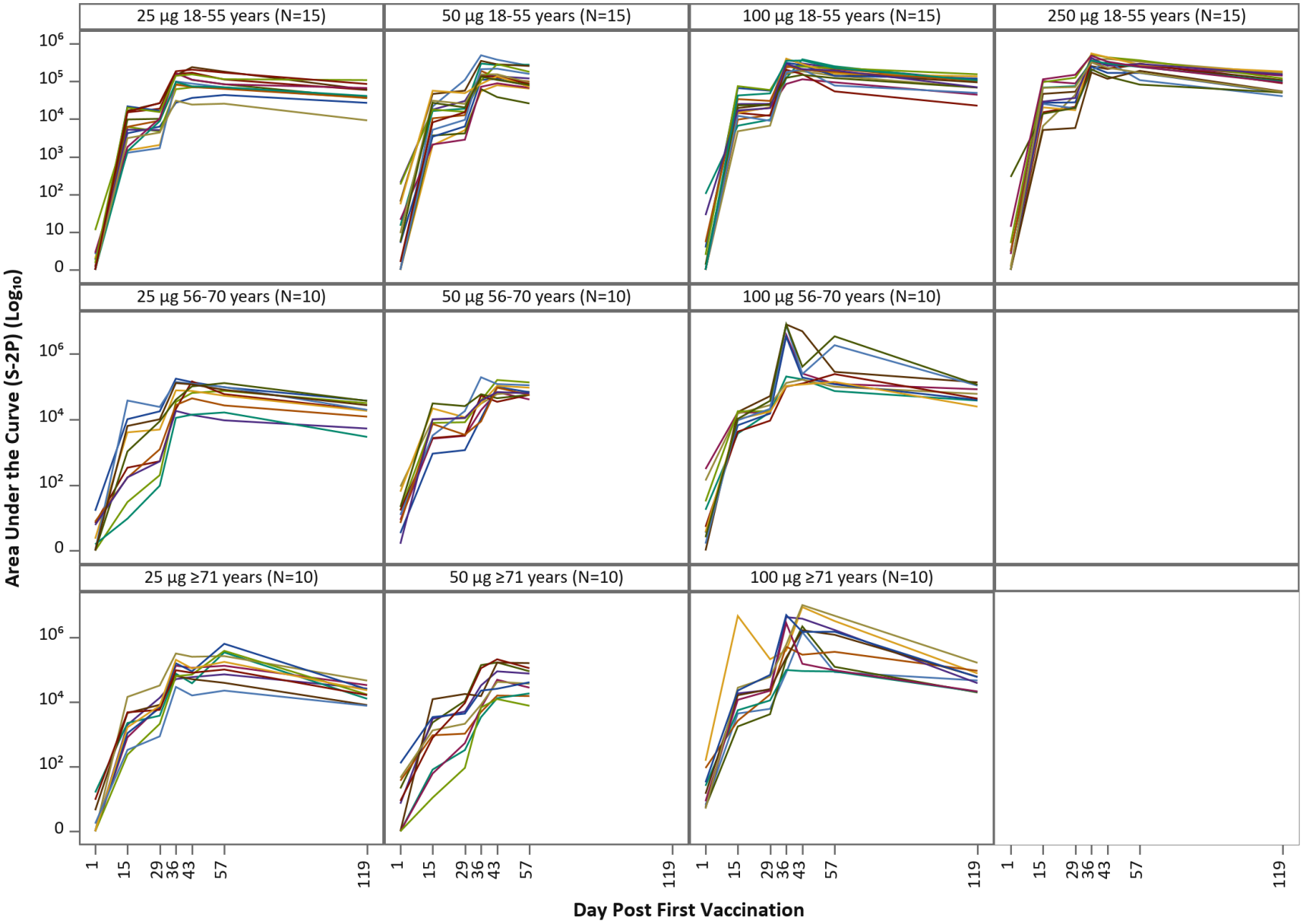


Figure 11: Serum IgG ELISA Area Under the Curve (AUC) Values by Time Point and Treatment Group – RBD, Per Protocol Population

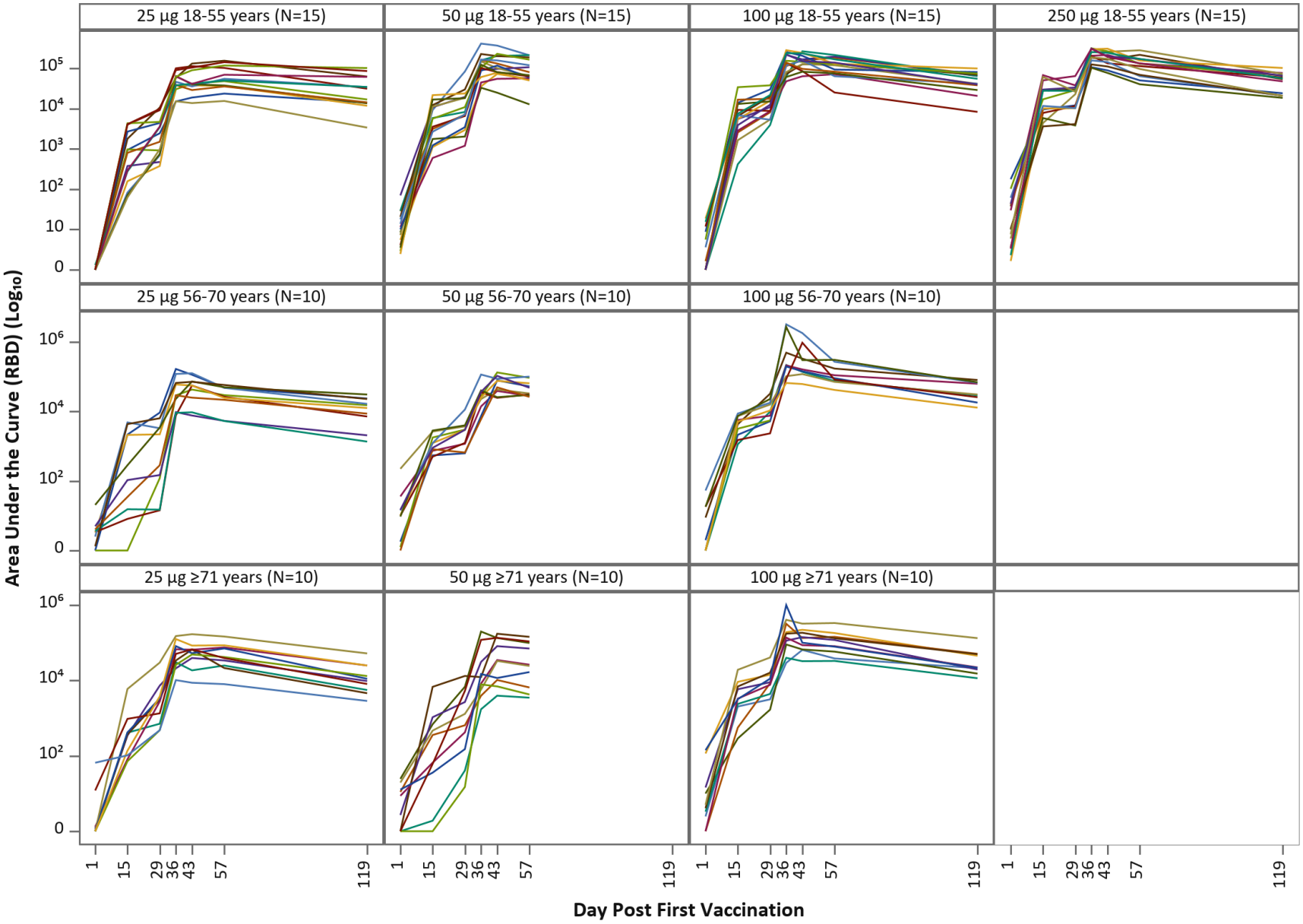


Figure 12: Pseudovirus Neutralization Assay Titers by Time Point and Treatment Group - ID50, Per Protocol Population

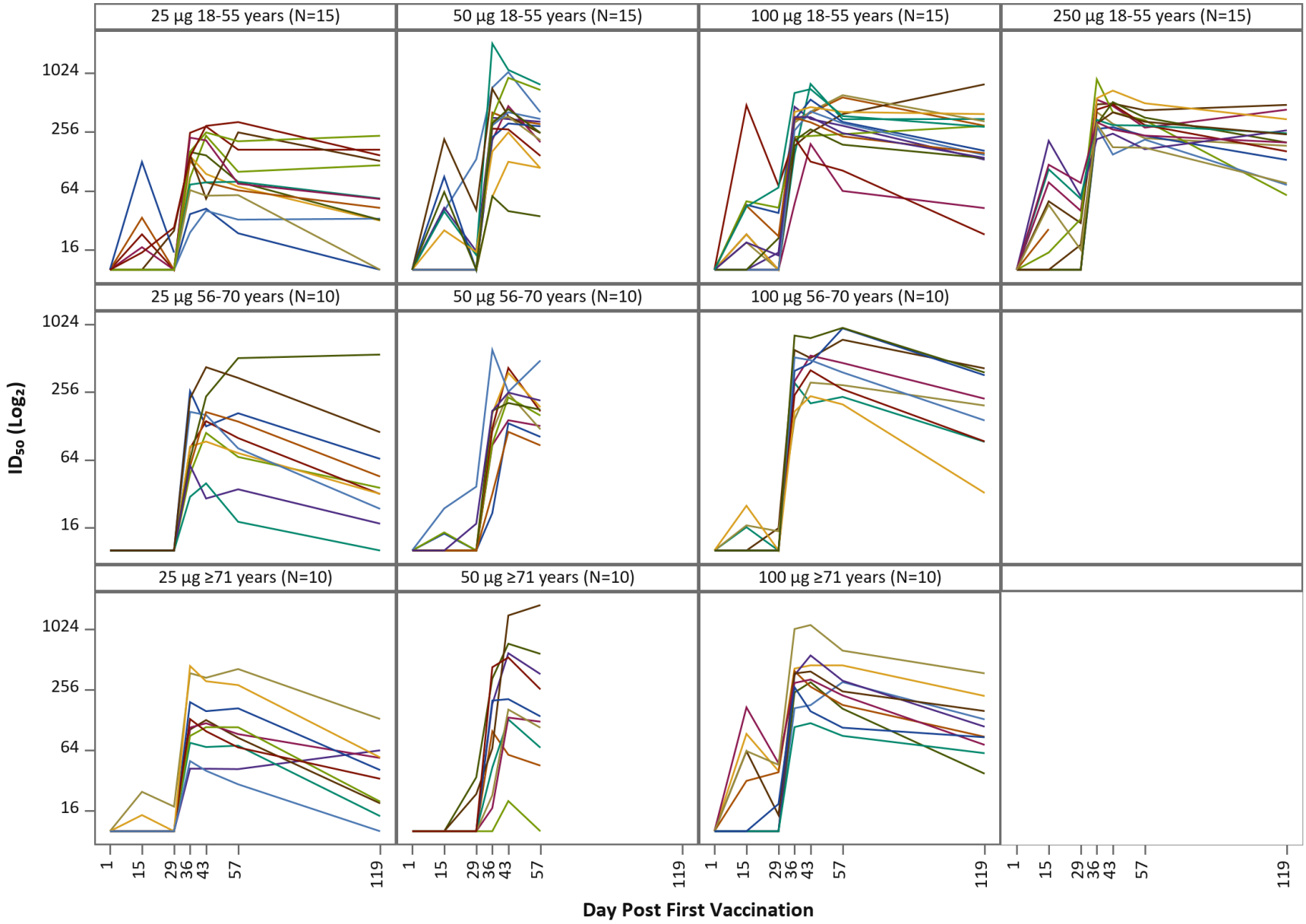


Figure 13: Pseudovirus Neutralization Assay Titers by Time Point and Treatment Group – ID80, Per Protocol Population

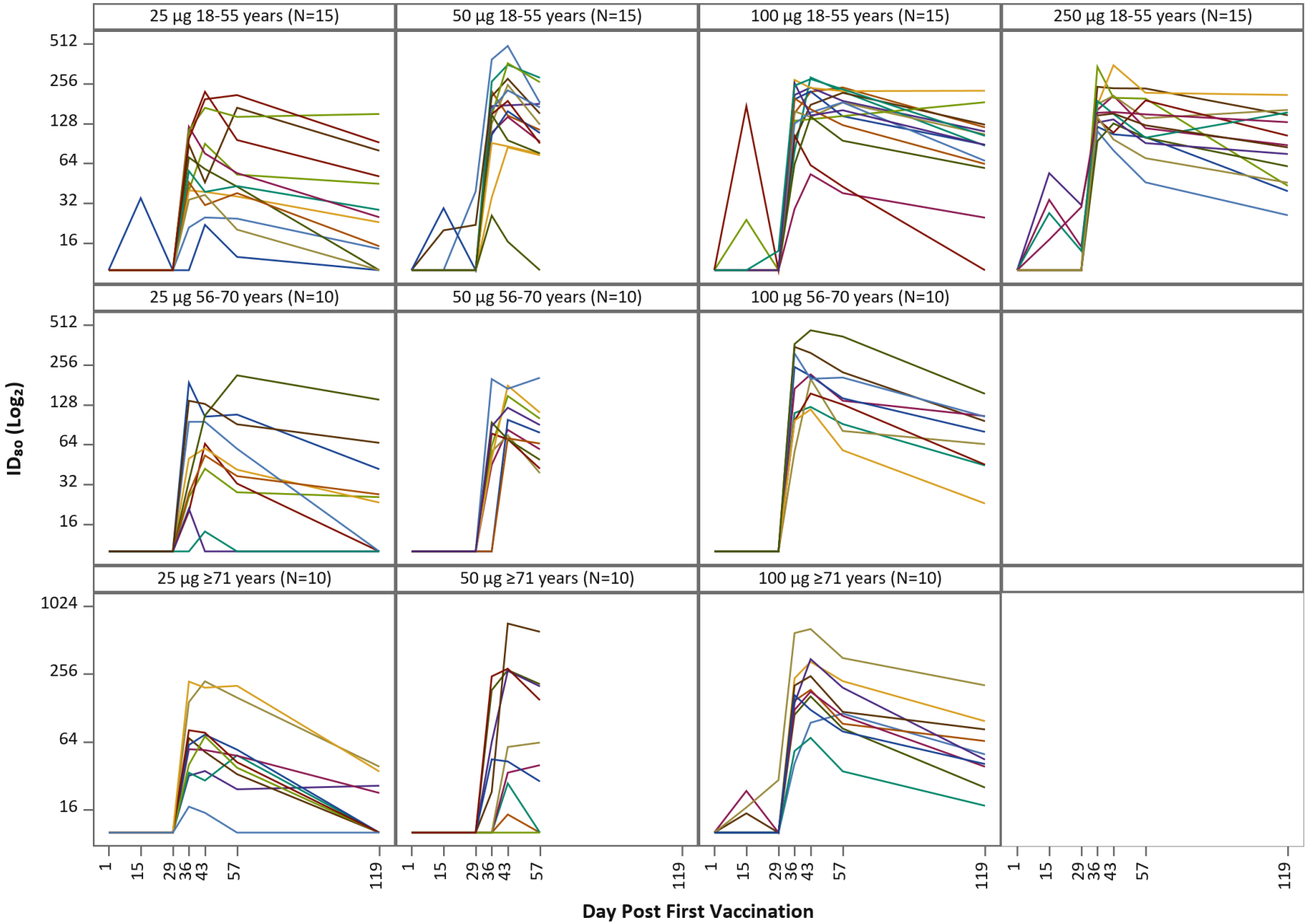


Figure 14: Geometric Mean Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

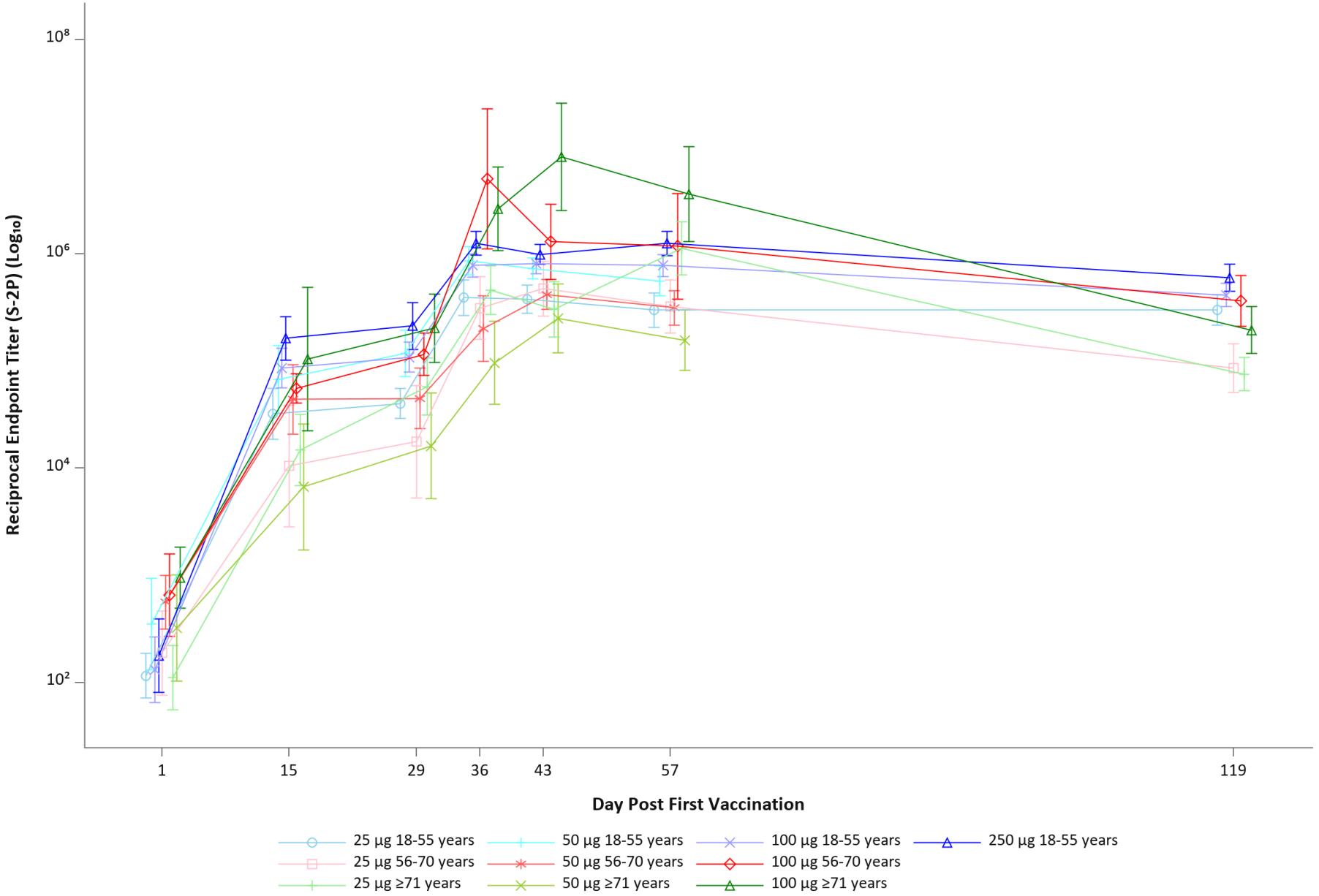


Figure 15: Geometric Mean Endpoint Titer Values by Time Point and Treatment Group - RBD, Per Protocol Population

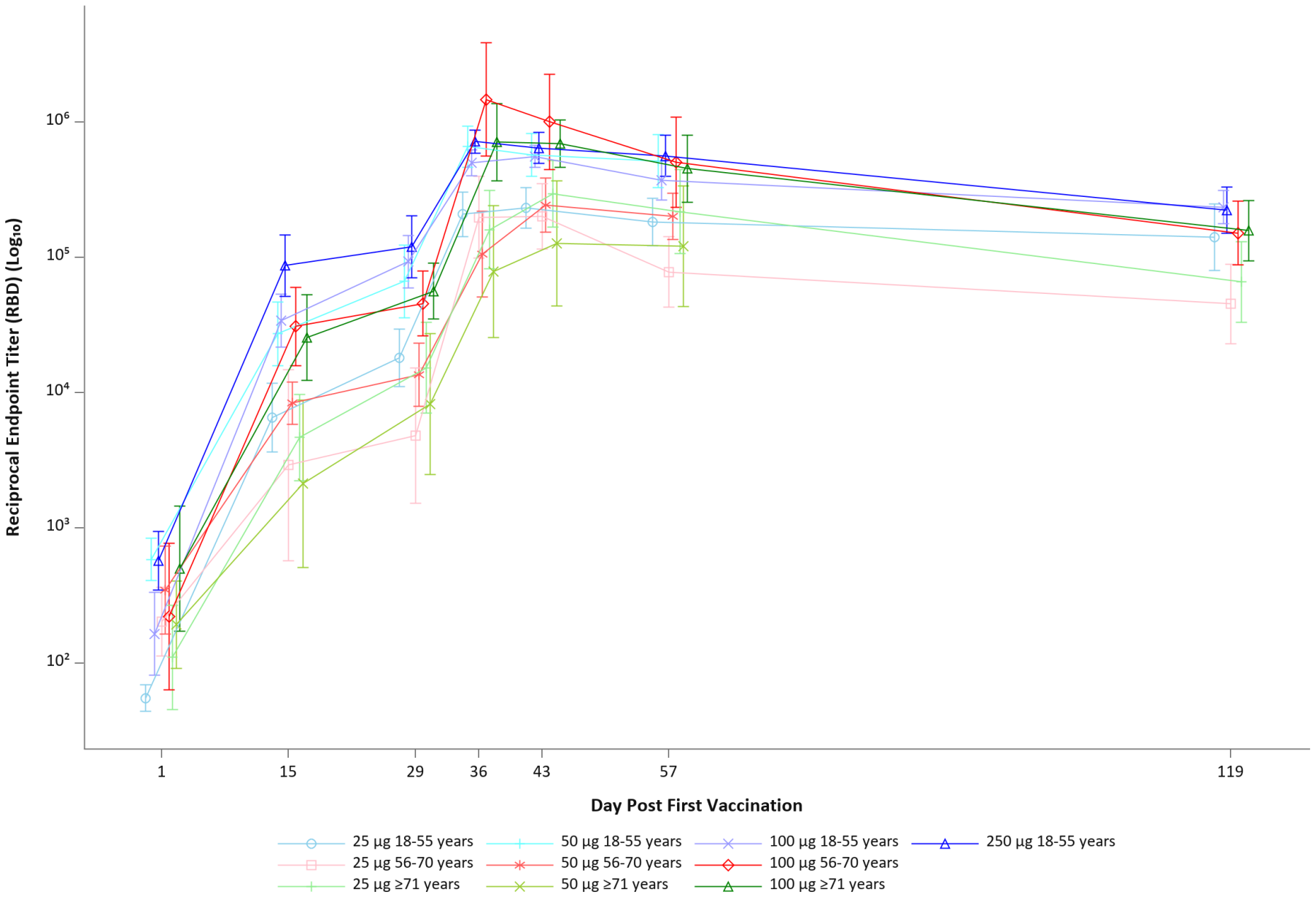


Figure 16: Geometric Mean Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

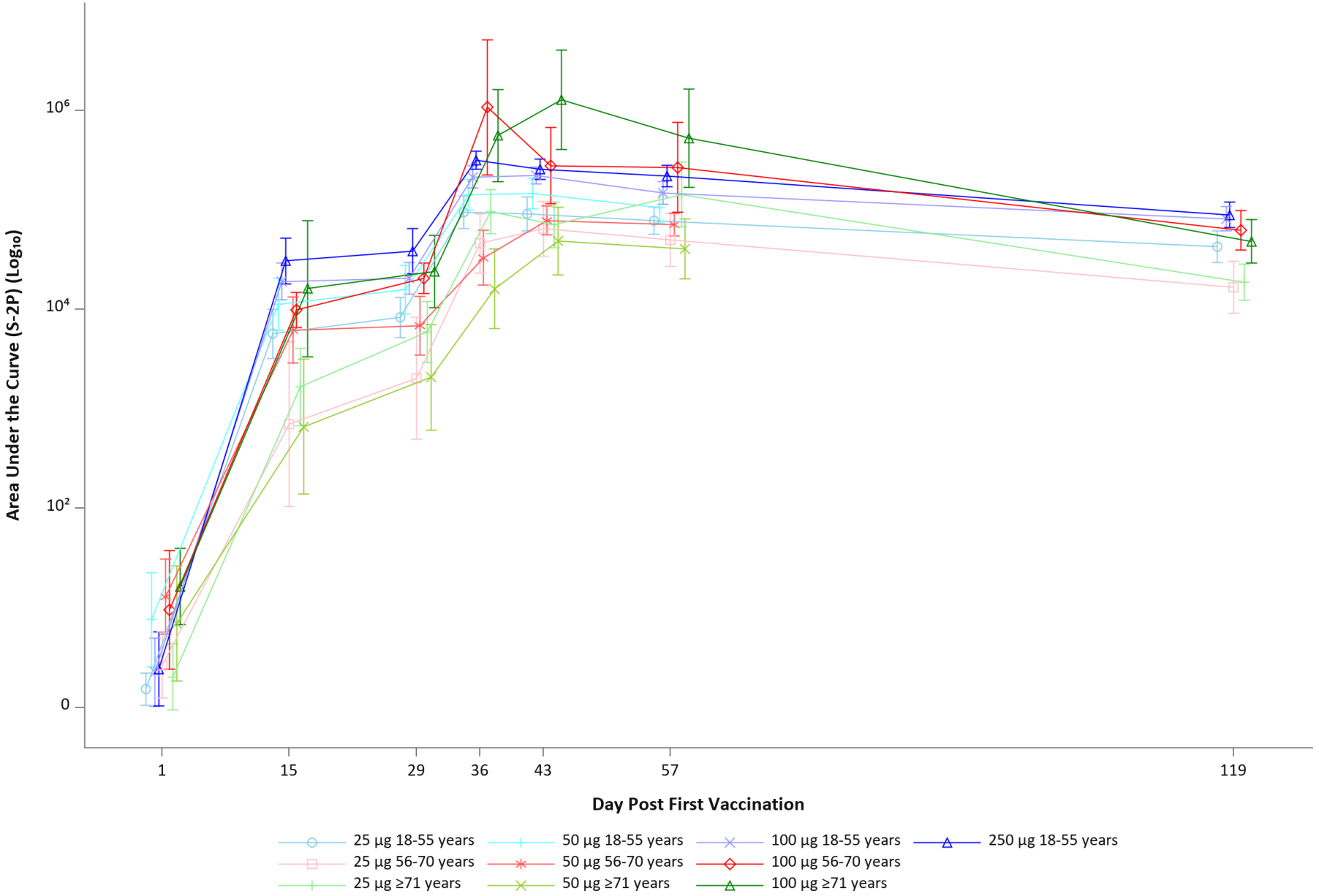


Figure 17: Geometric Mean Area Under the Curve (AUC) Values by Time Point and Treatment Group - RBD, Per Protocol Population

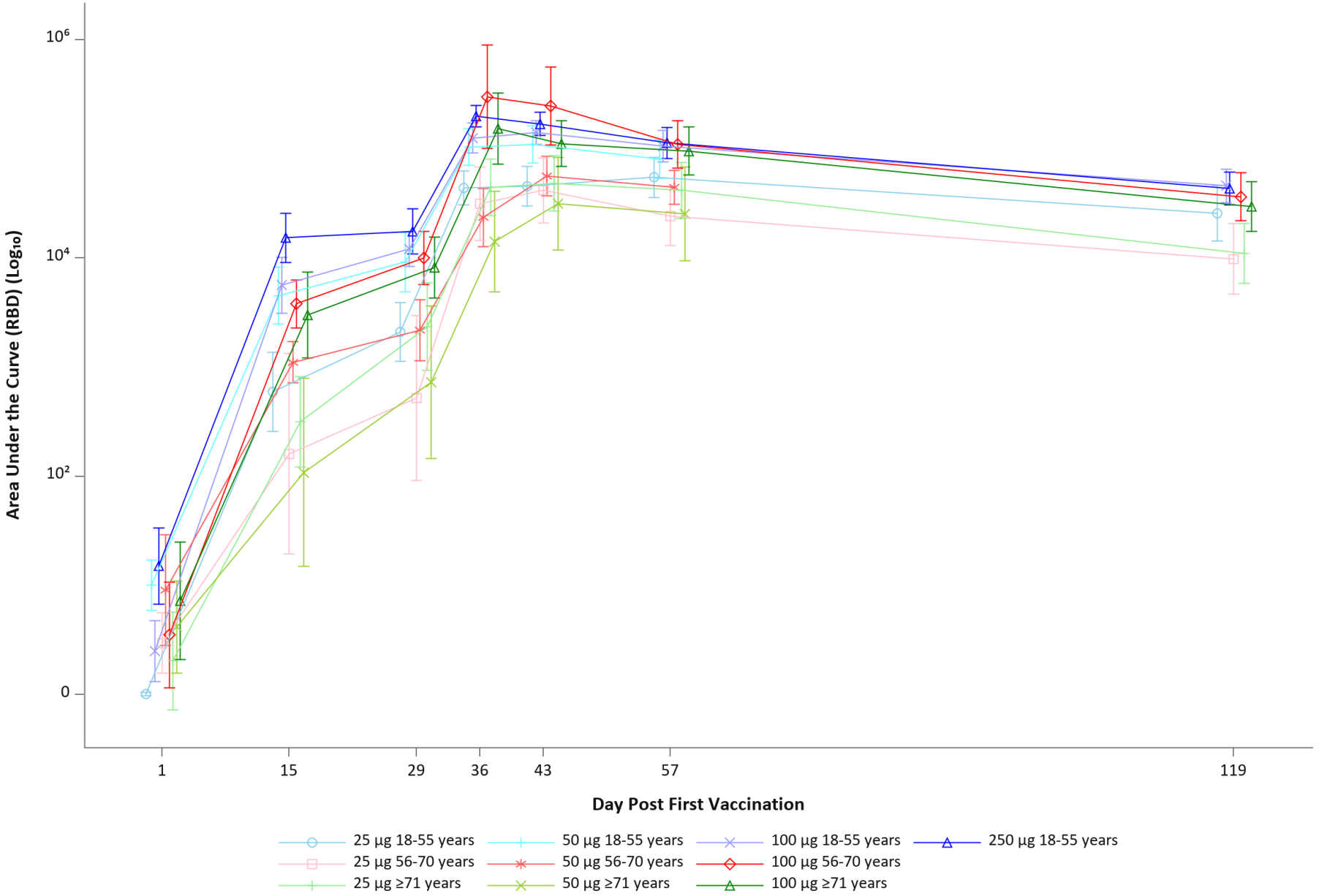


Figure 18: Pseudovirus Neutralization Assay GM by Time Point and Treatment Group - ID_{50}, Per Protocol Population

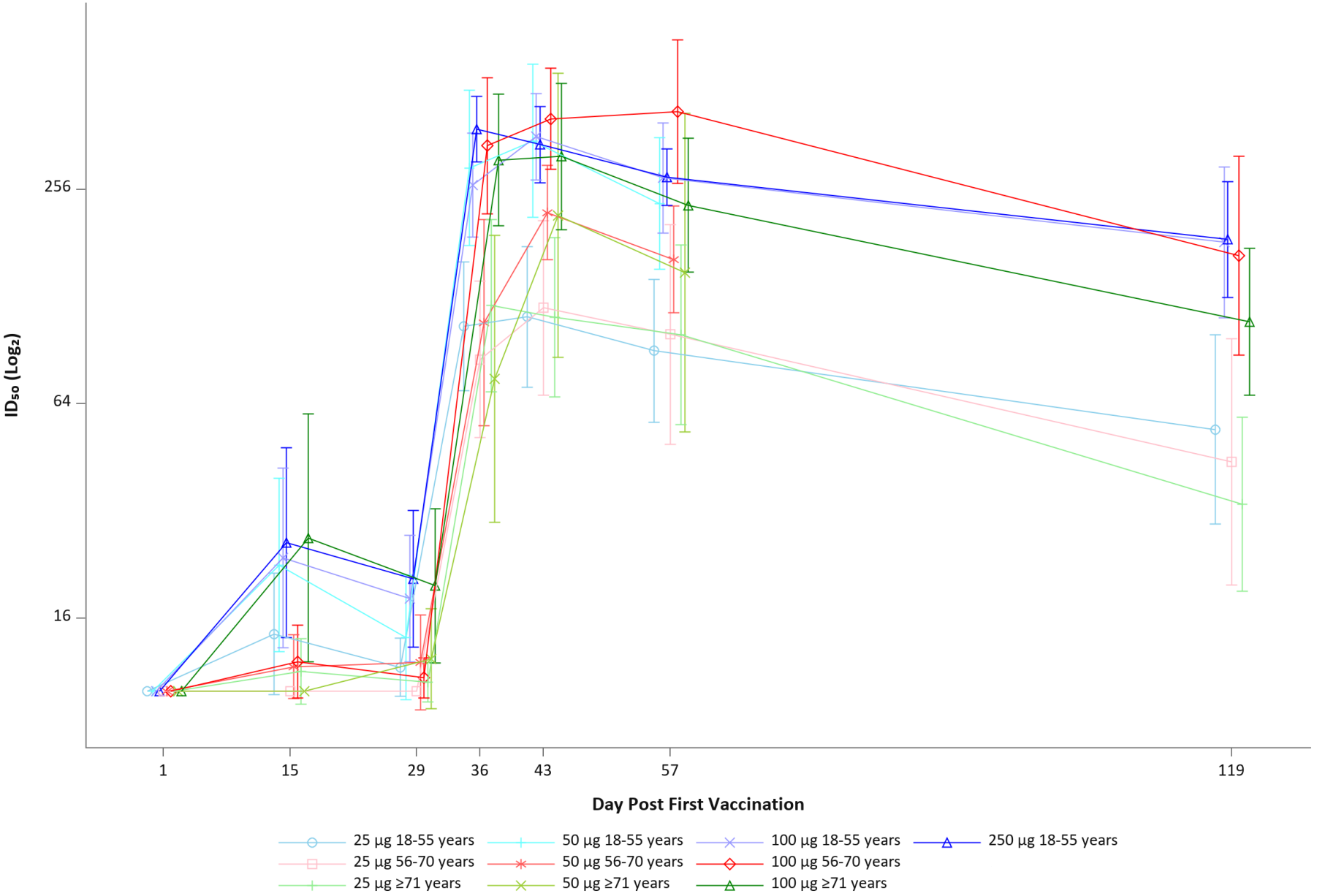


Figure 19: Pseudovirus Neutralization Assay GM by Time Point and Treatment Group - ID_{80}, Per Protocol Population

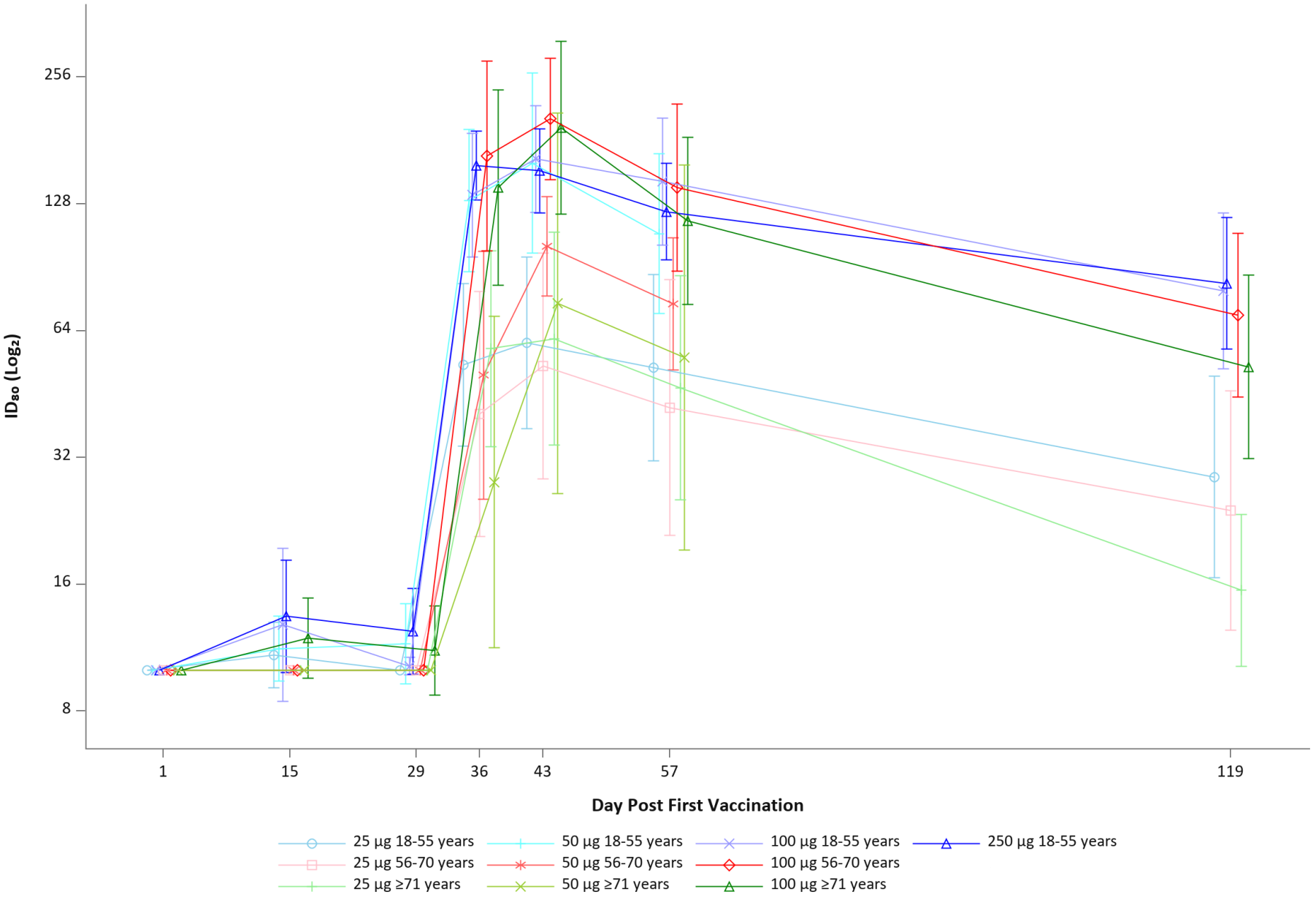


Figure 20: Plaque Reduction Neutralization Test Geometric Mean by Time Point and Treatment Group - $PRNT_{80}$, Per Protocol Population

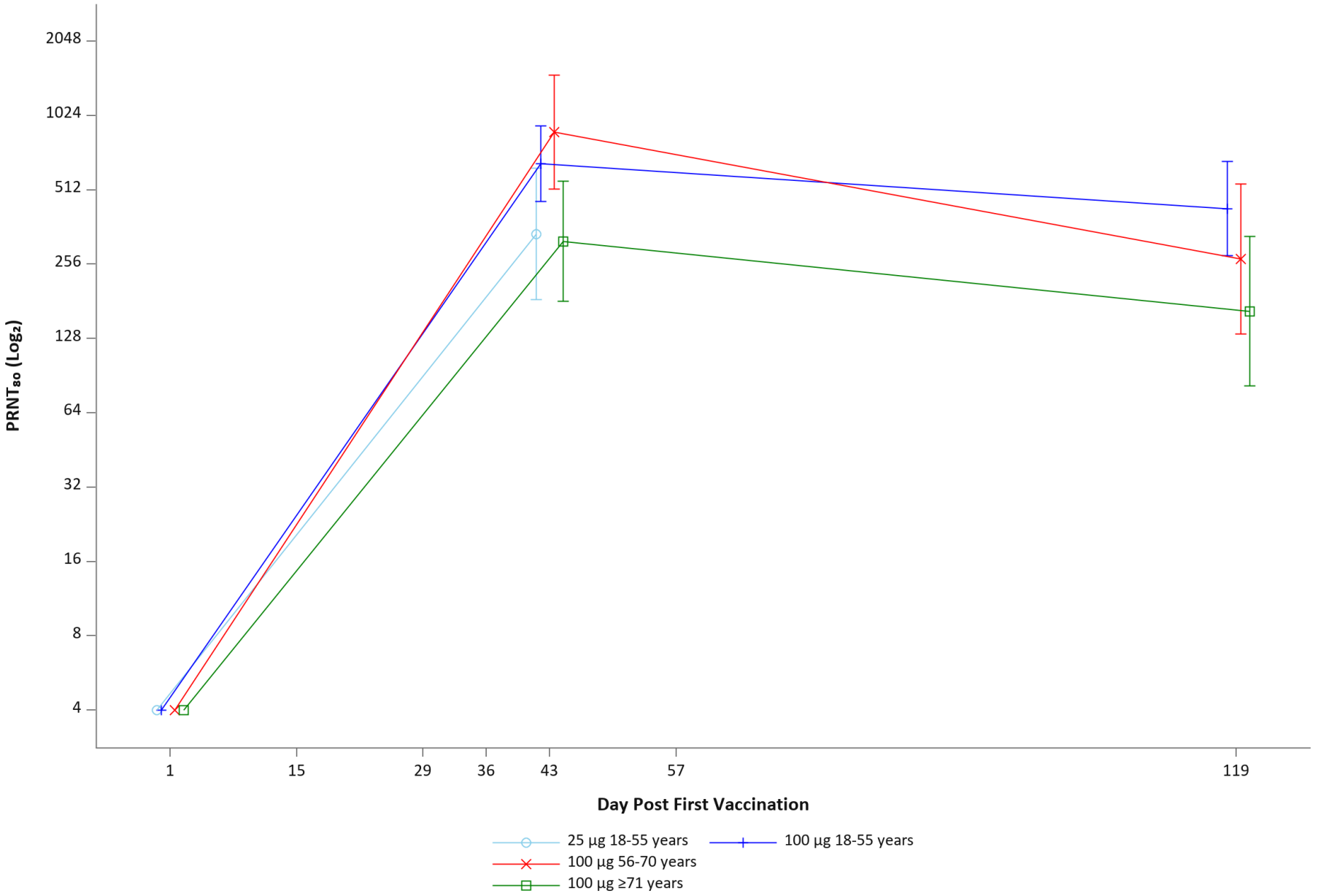


Figure 21: FRNT GM by Time Point and Treatment Group - ID_{50}, Per Protocol Population

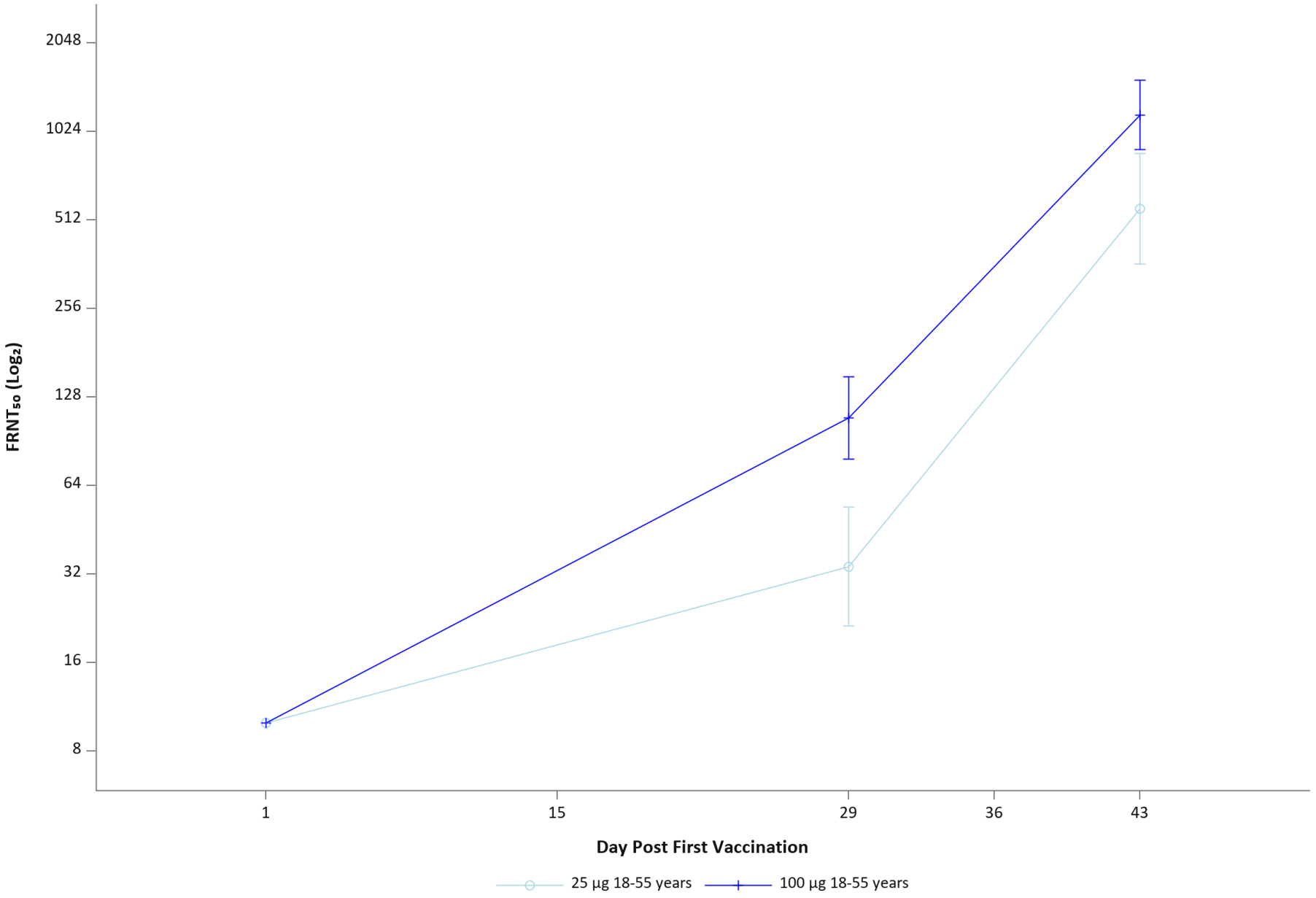


Figure 22: FRNT-mNG Geometric Mean by Time Point and Treatment Group - ID_{50}, Per Protocol Population

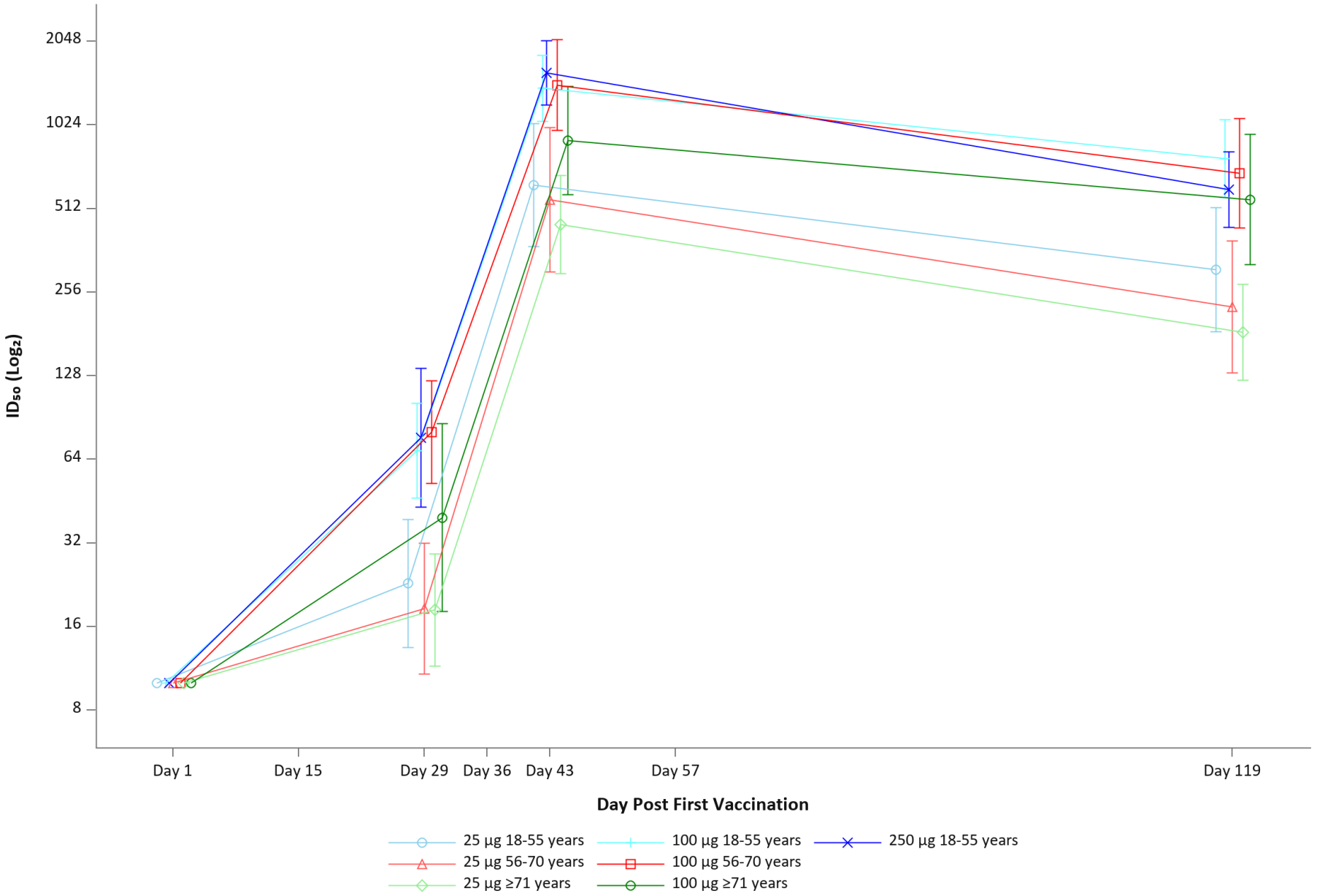


Figure 23: FRNT-mNG Geometric Mean by Time Point and Treatment Group - ID_{80}, Per Protocol Population

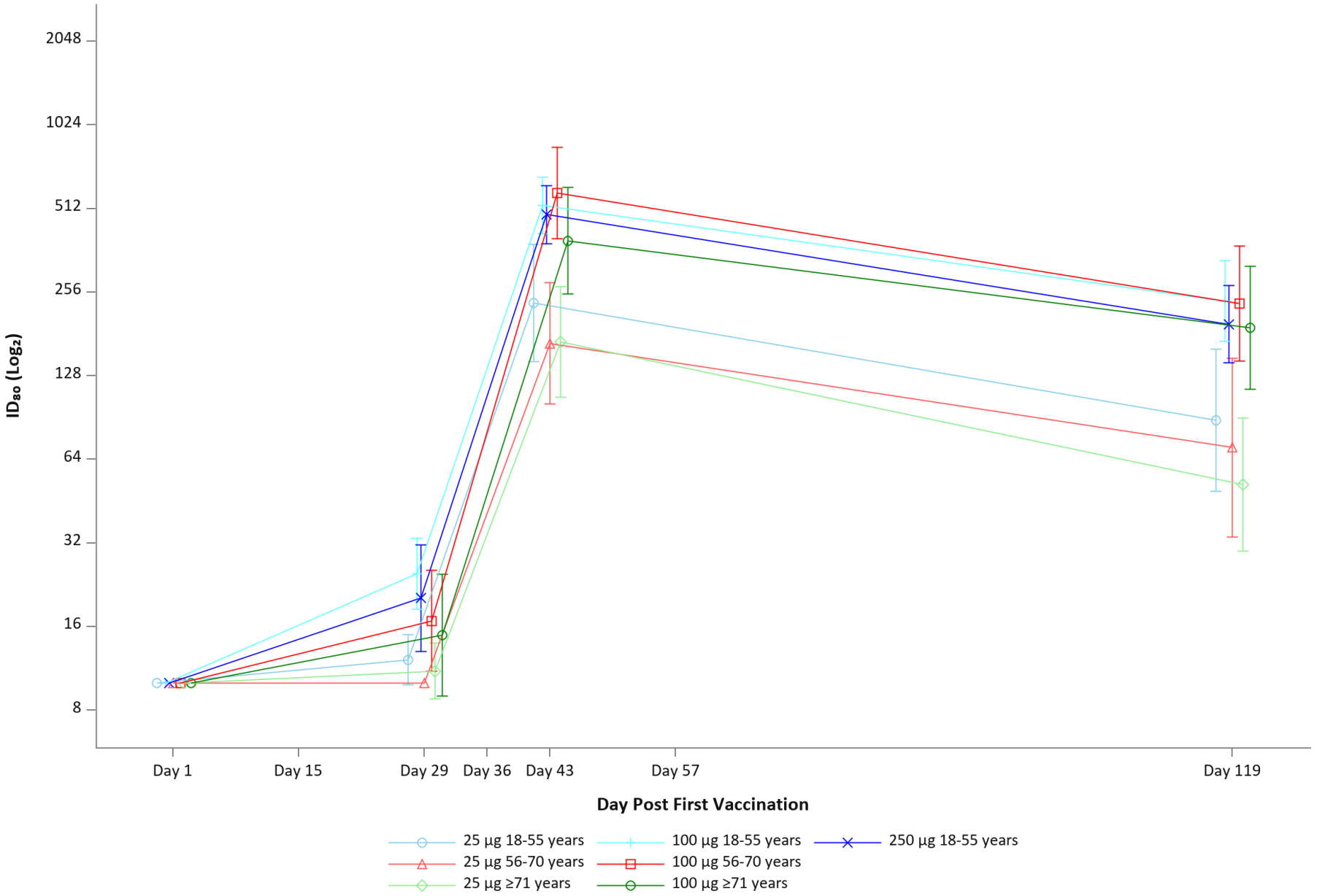


Figure 24: nLuciferase Neutralization Assay Geometric Mean by Time Point and Treatment Group - ID_{50}, Per Protocol Population

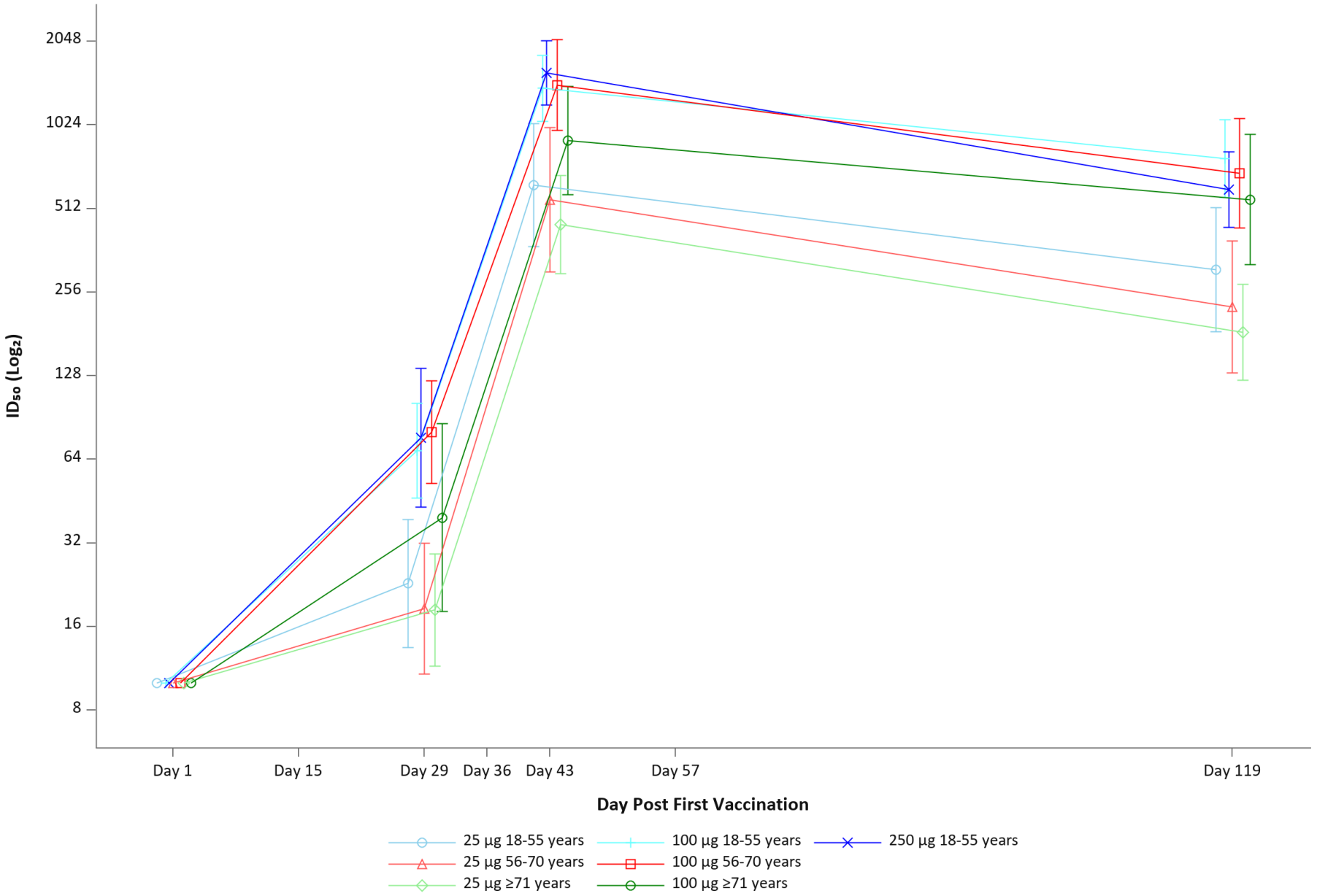


Figure 25: nLuciferase Neutralization Assay Geometric Mean by Time Point and Treatment Group - ID_{80}, Per Protocol Population

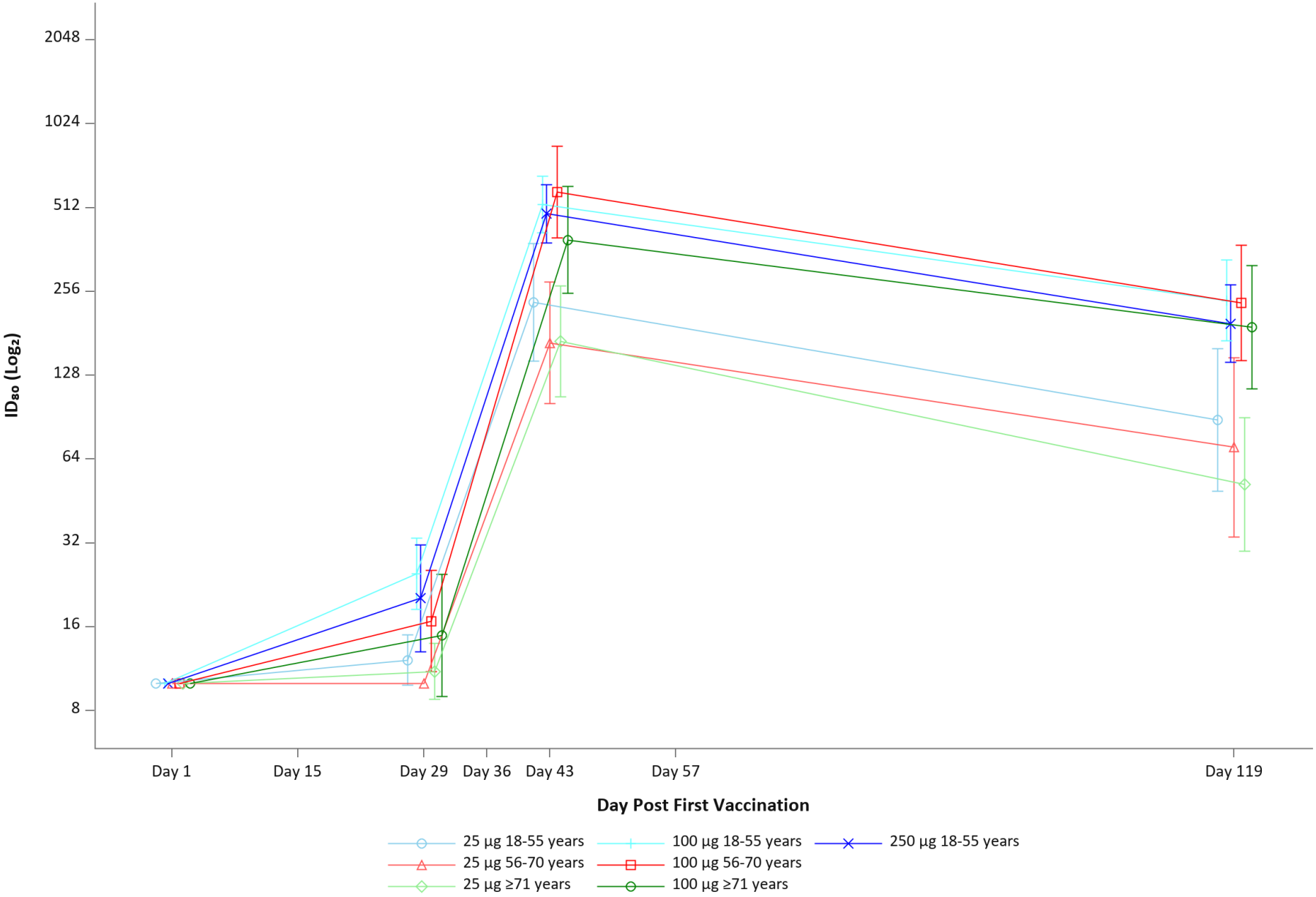


Figure 26: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age 18-55, Per Protocol Population

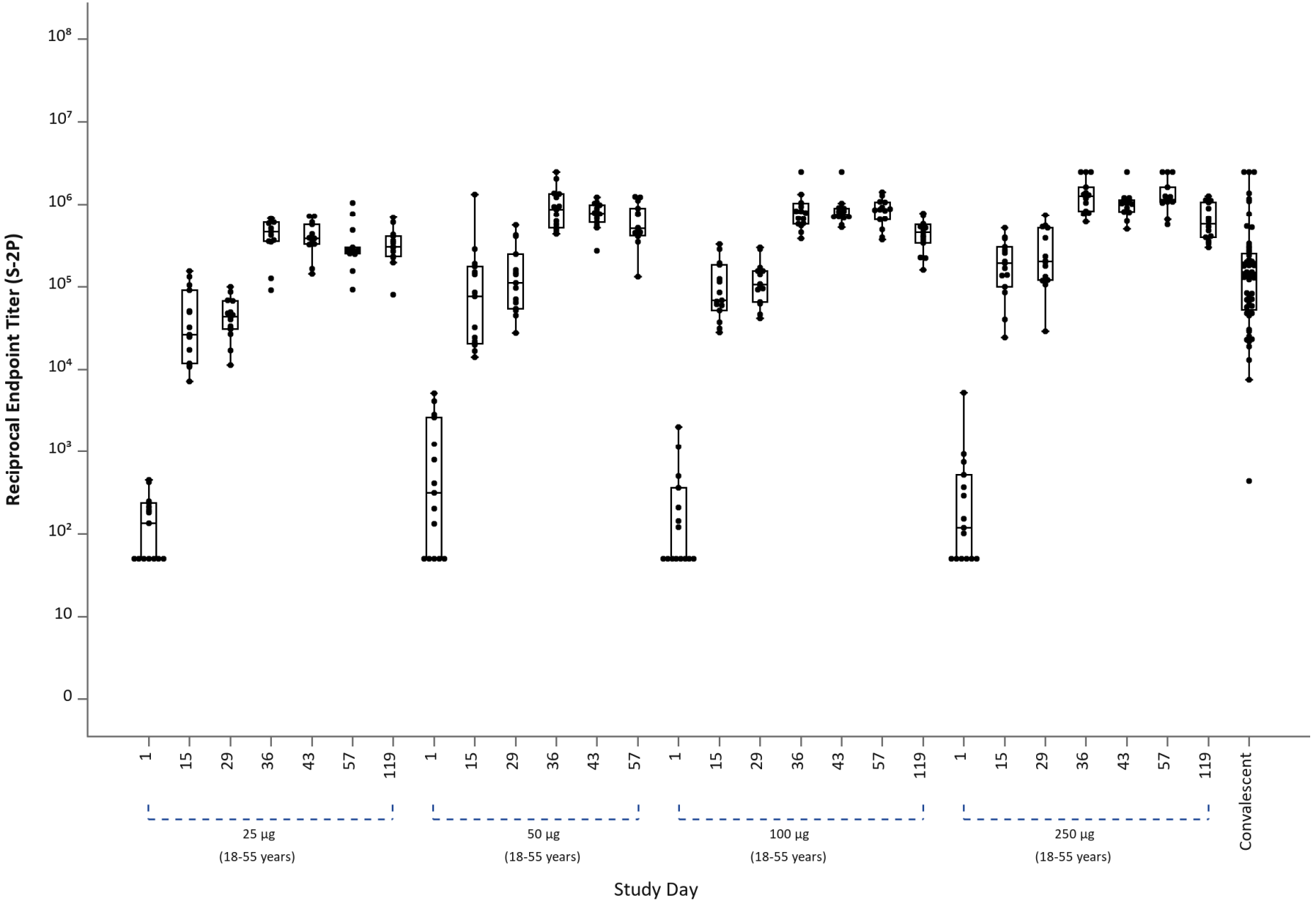


Figure 27: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age 56-70, Per Protocol Population

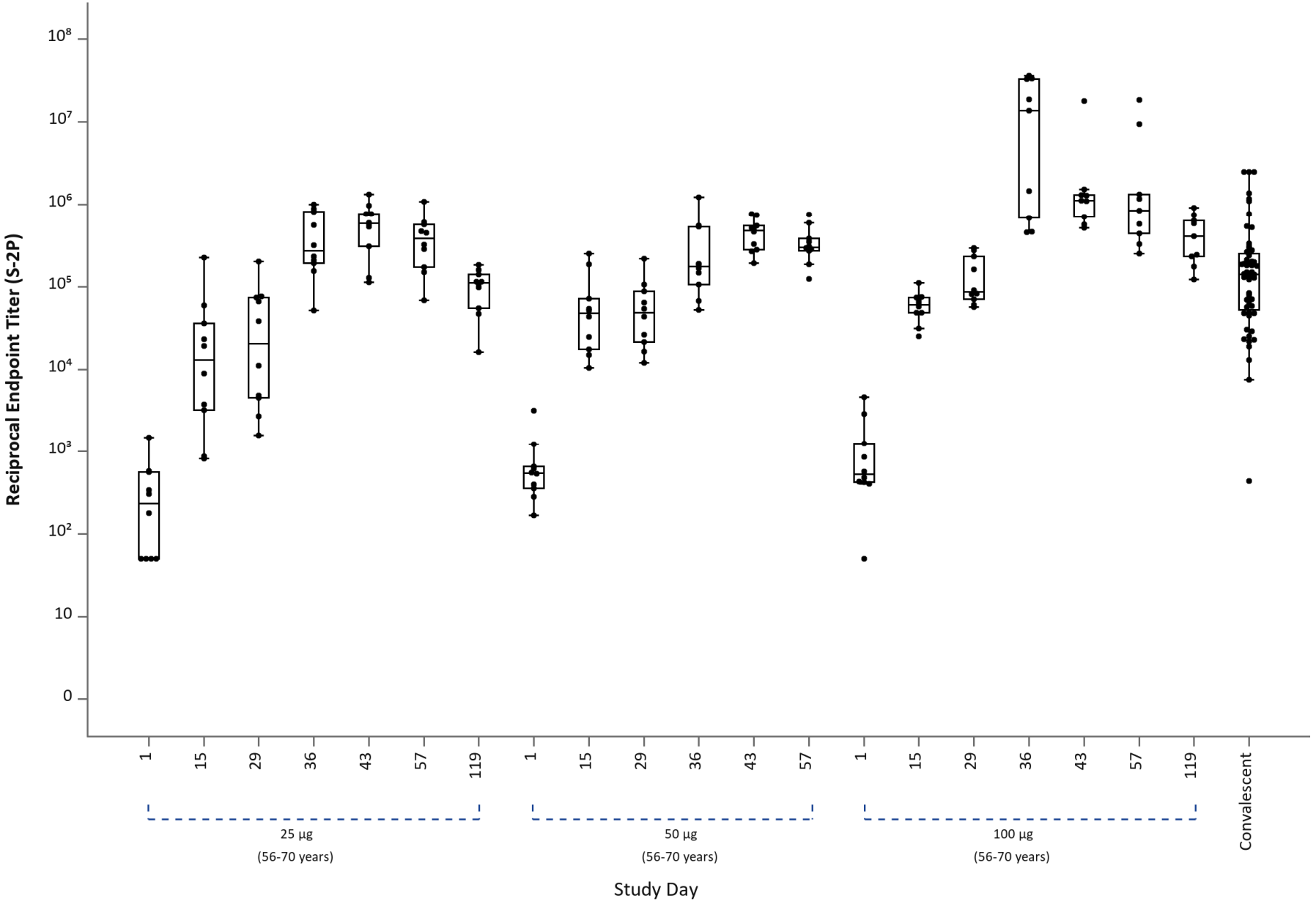


Figure 28: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age ≥71, Per Protocol Population

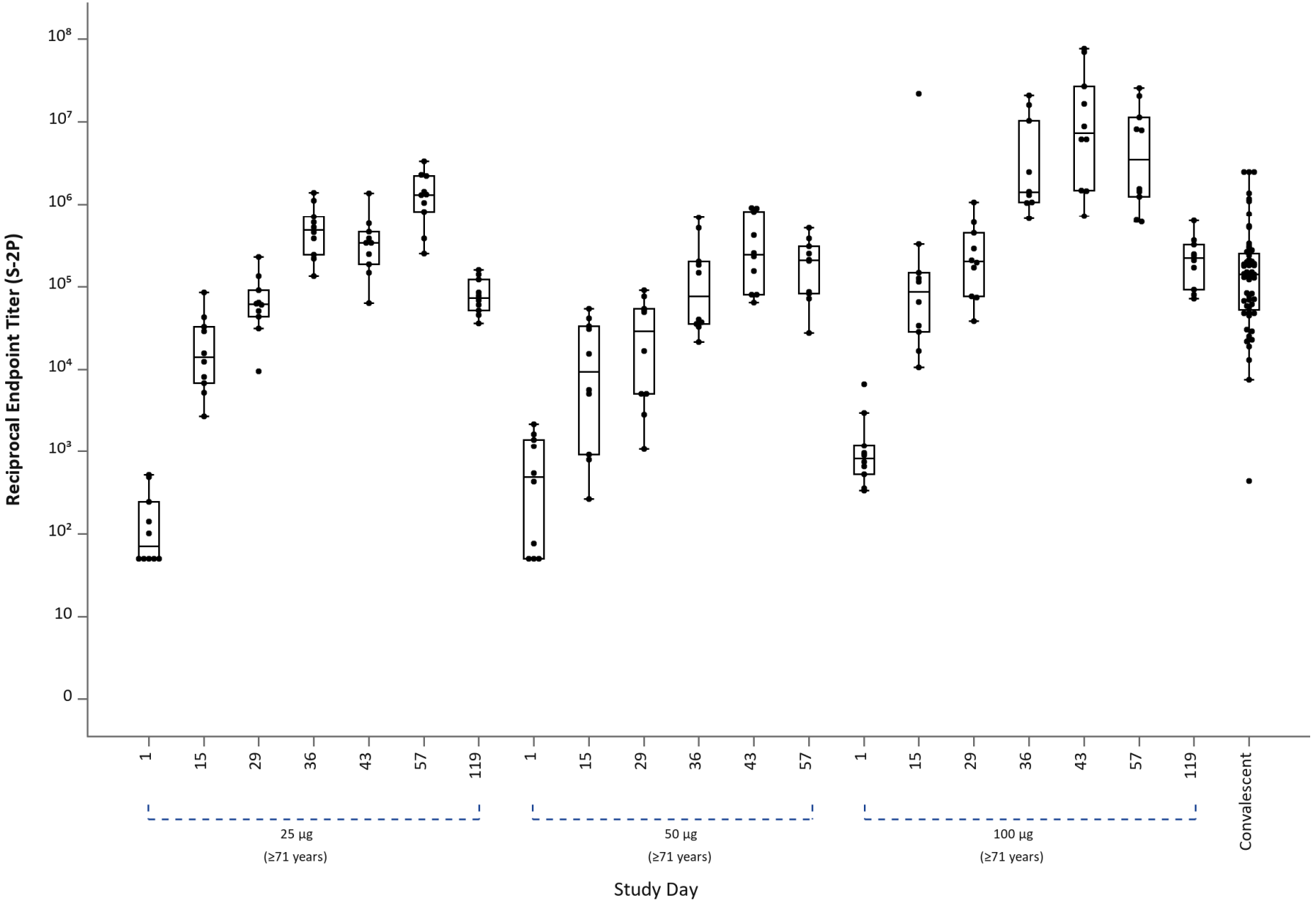


Figure 29: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age 18-55, Per Protocol Population

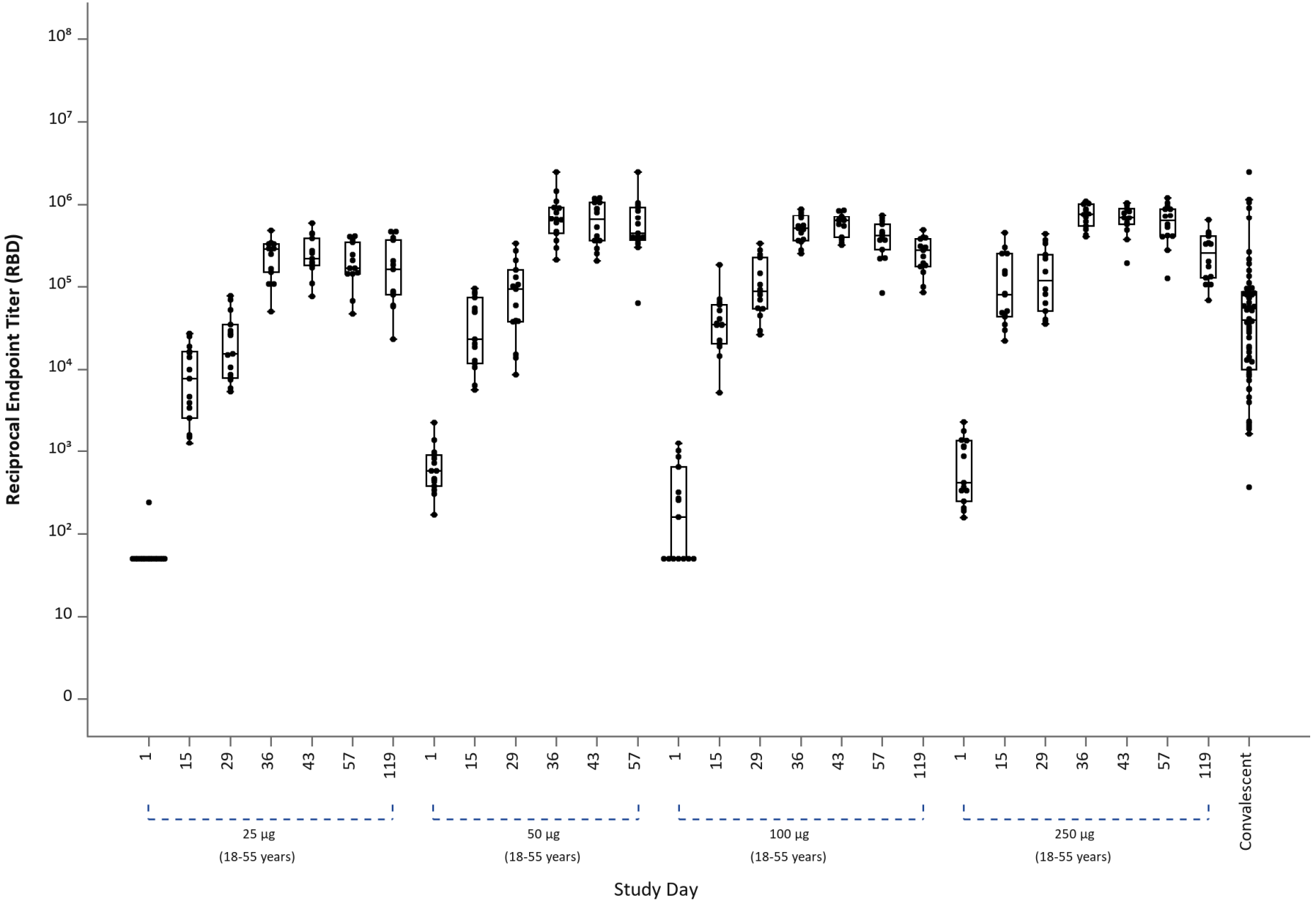


Figure 30: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age 56-70, Per Protocol Population

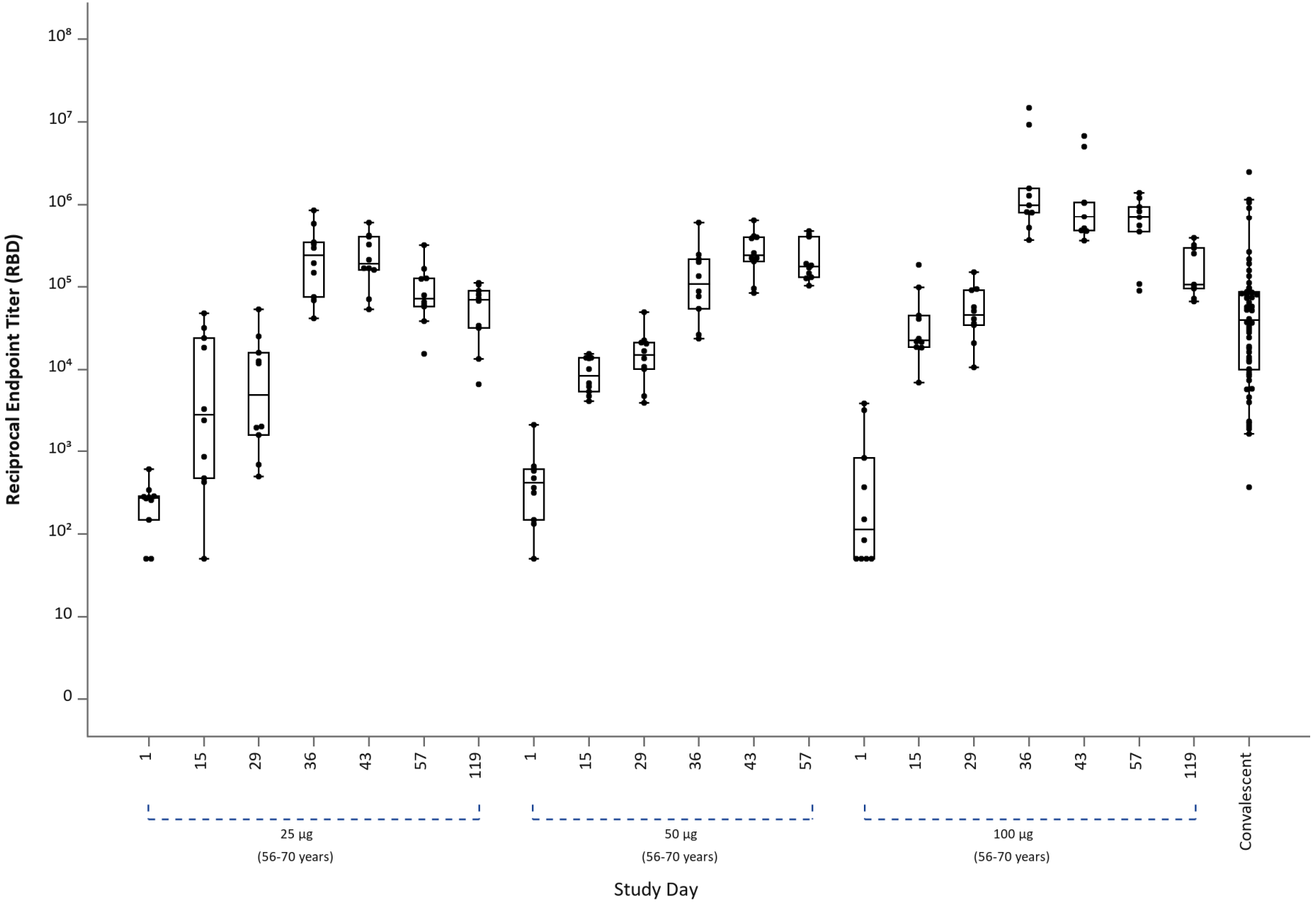


Figure 31: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age ≥71, Per Protocol Population

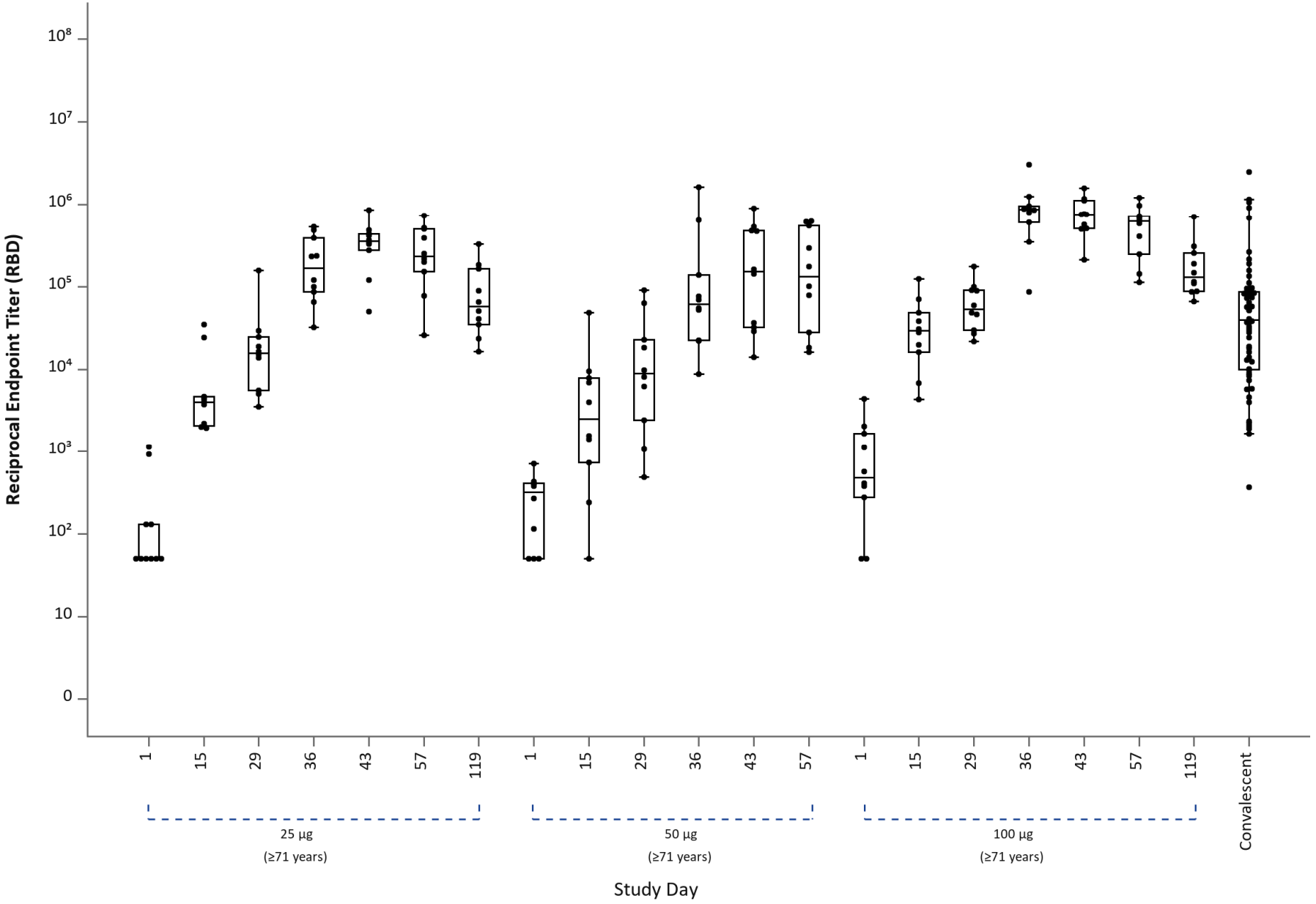


Figure 32: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age 18-55, Per Protocol Population

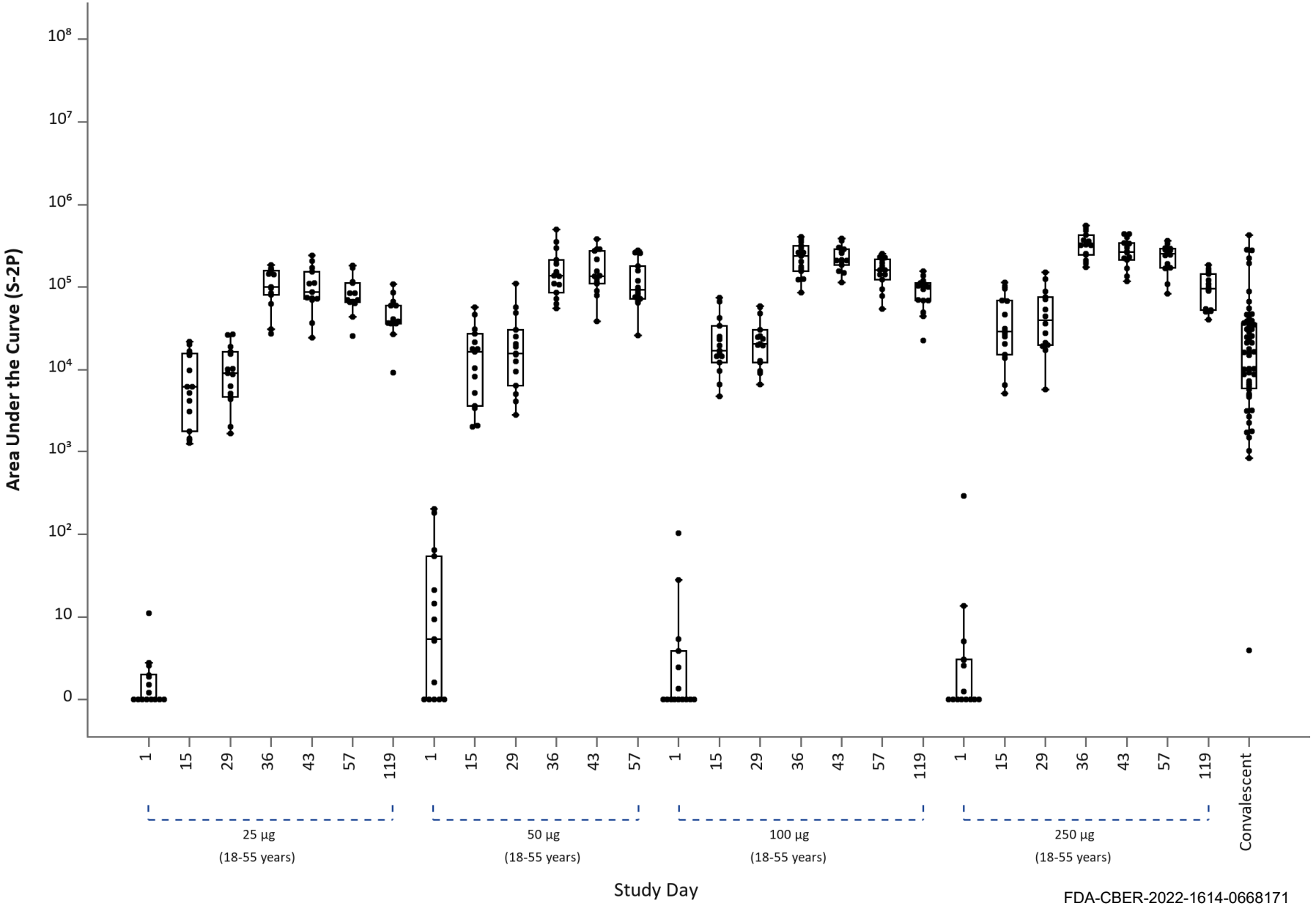


Figure 33: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age 56-70, Per Protocol Population

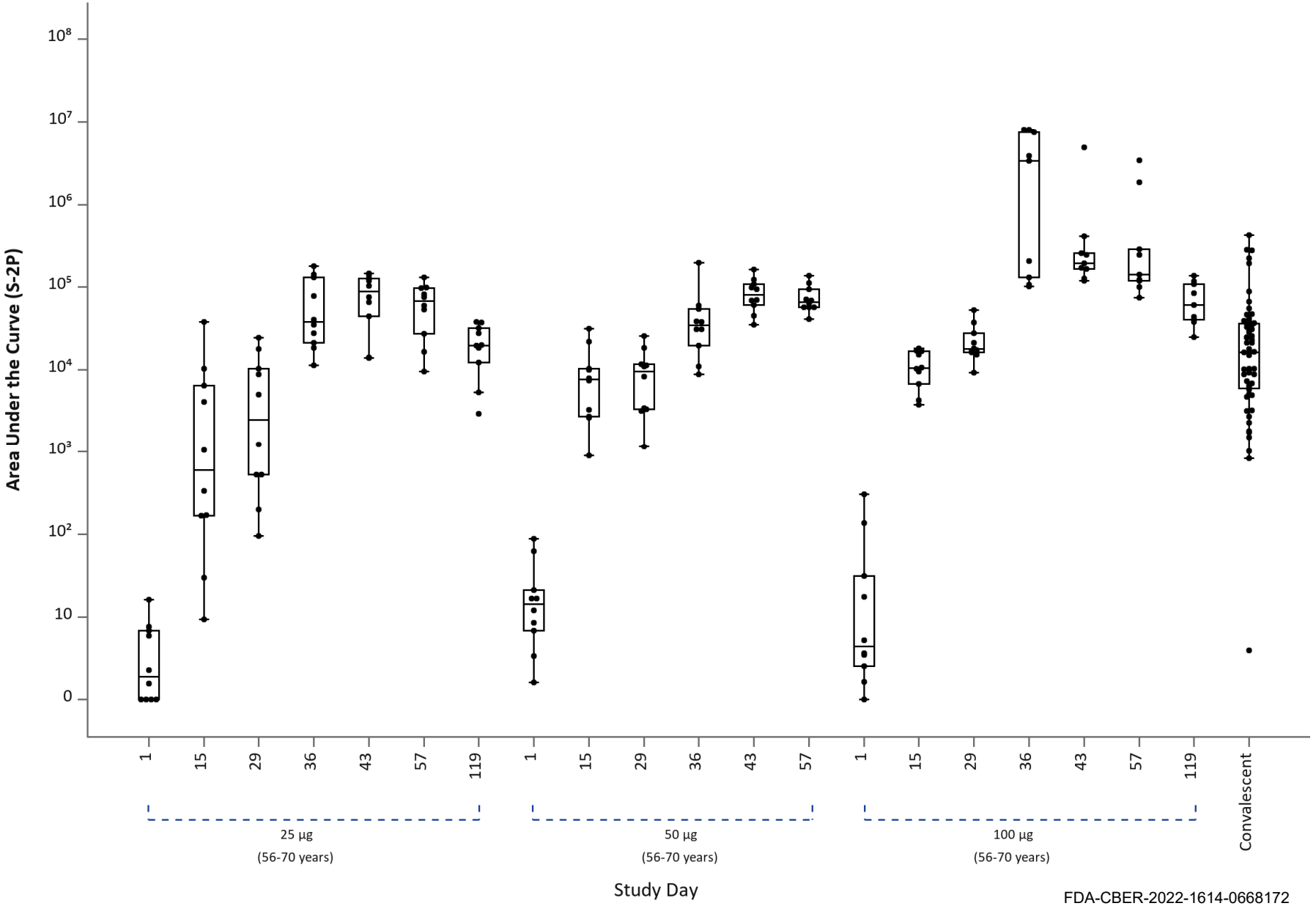


Figure 34: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age ≥71, Per Protocol Population

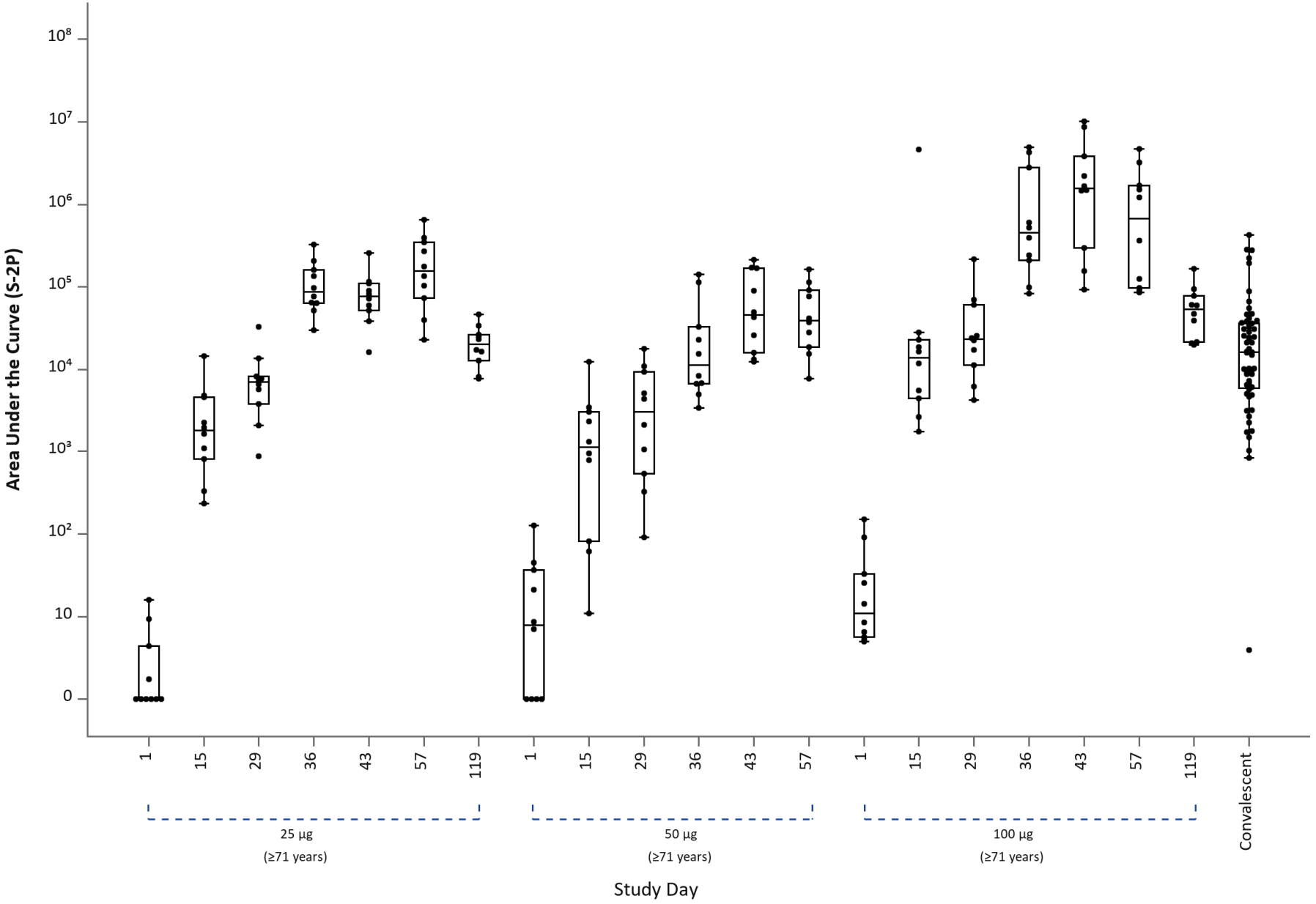


Figure 35: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age 18-55, Per Protocol Population

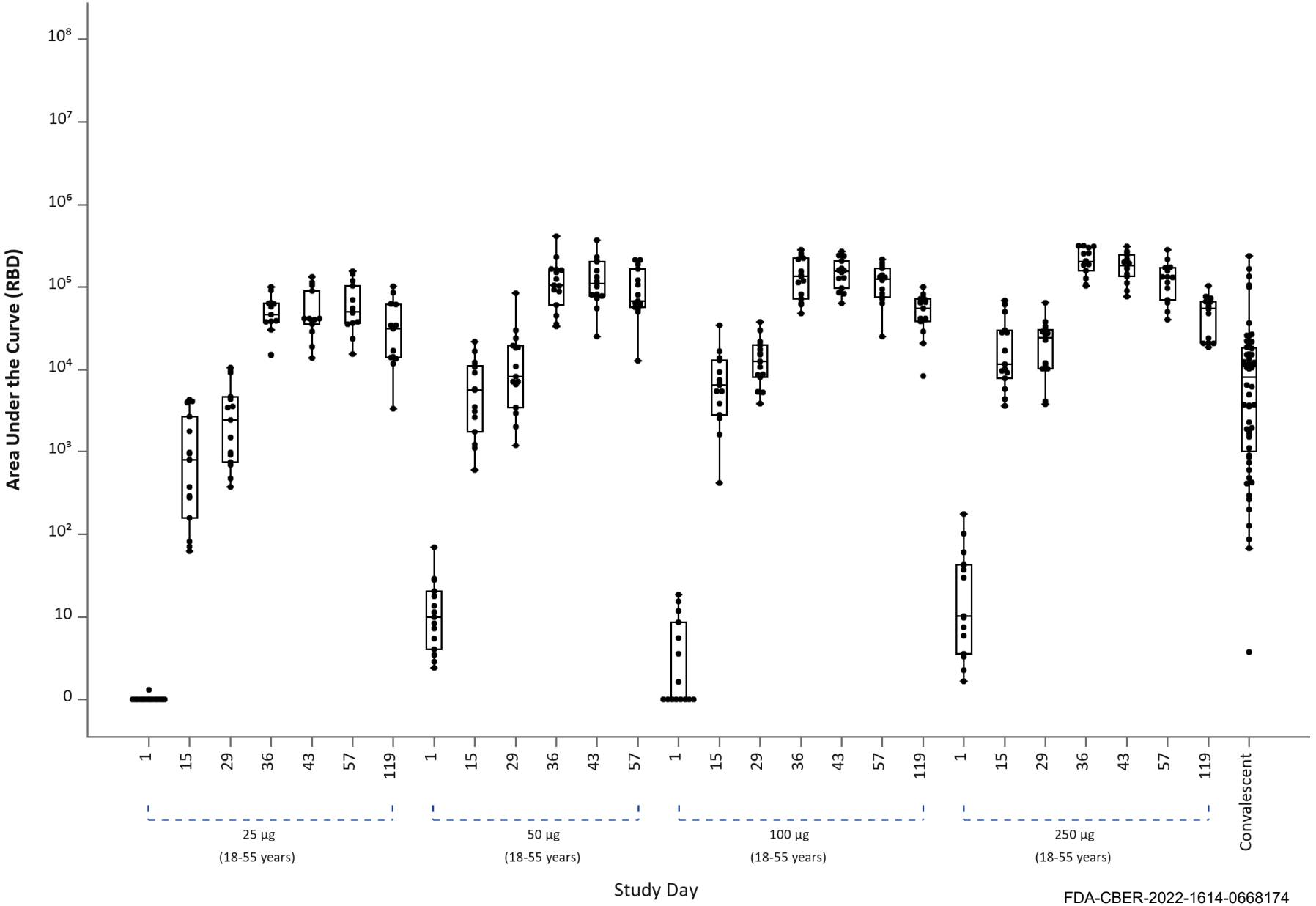


Figure 36: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age 56-70, Per Protocol Population

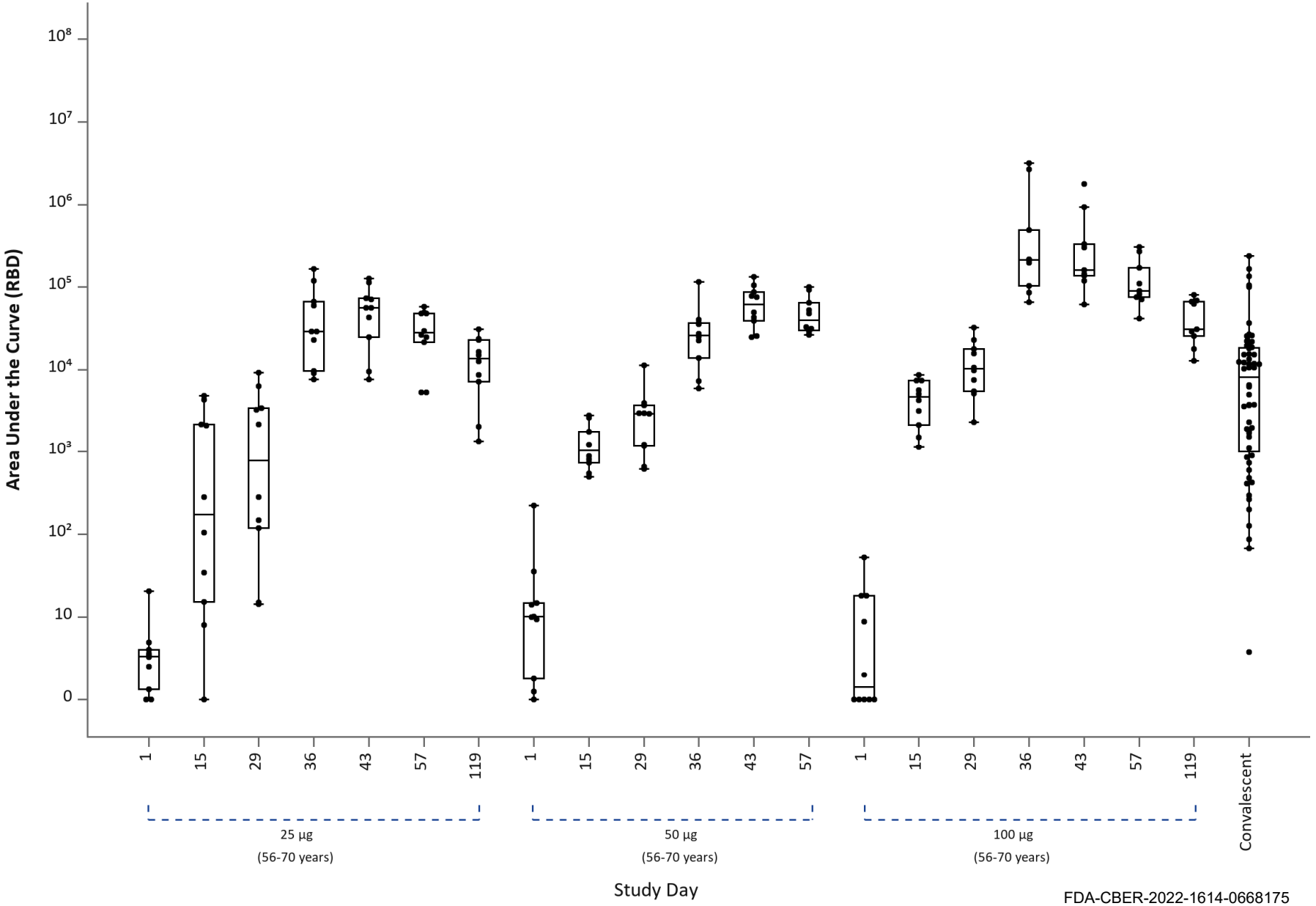


Figure 37: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age ≥71, Per Protocol Population

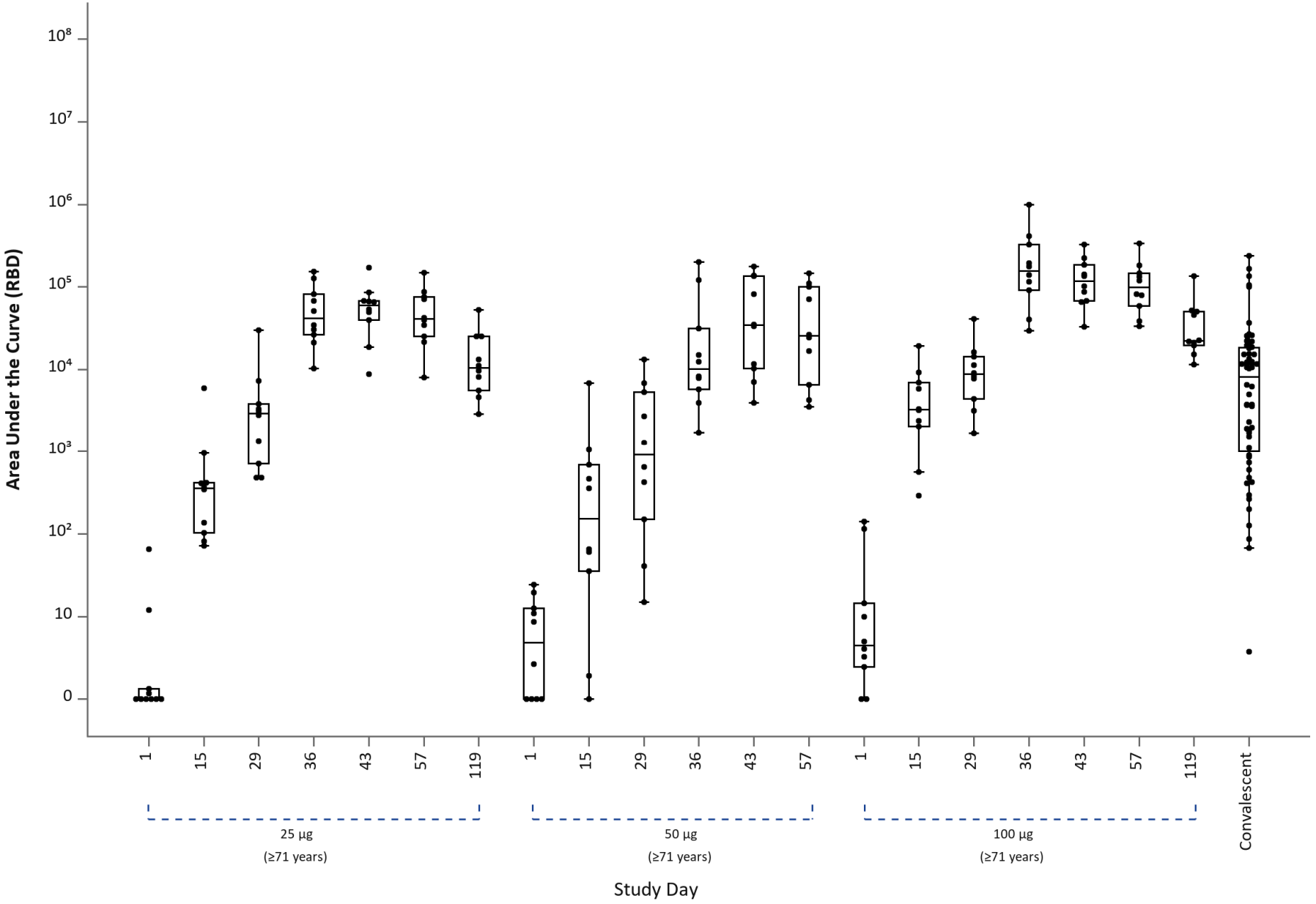


Figure 38: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 18-55, Per Protocol Population

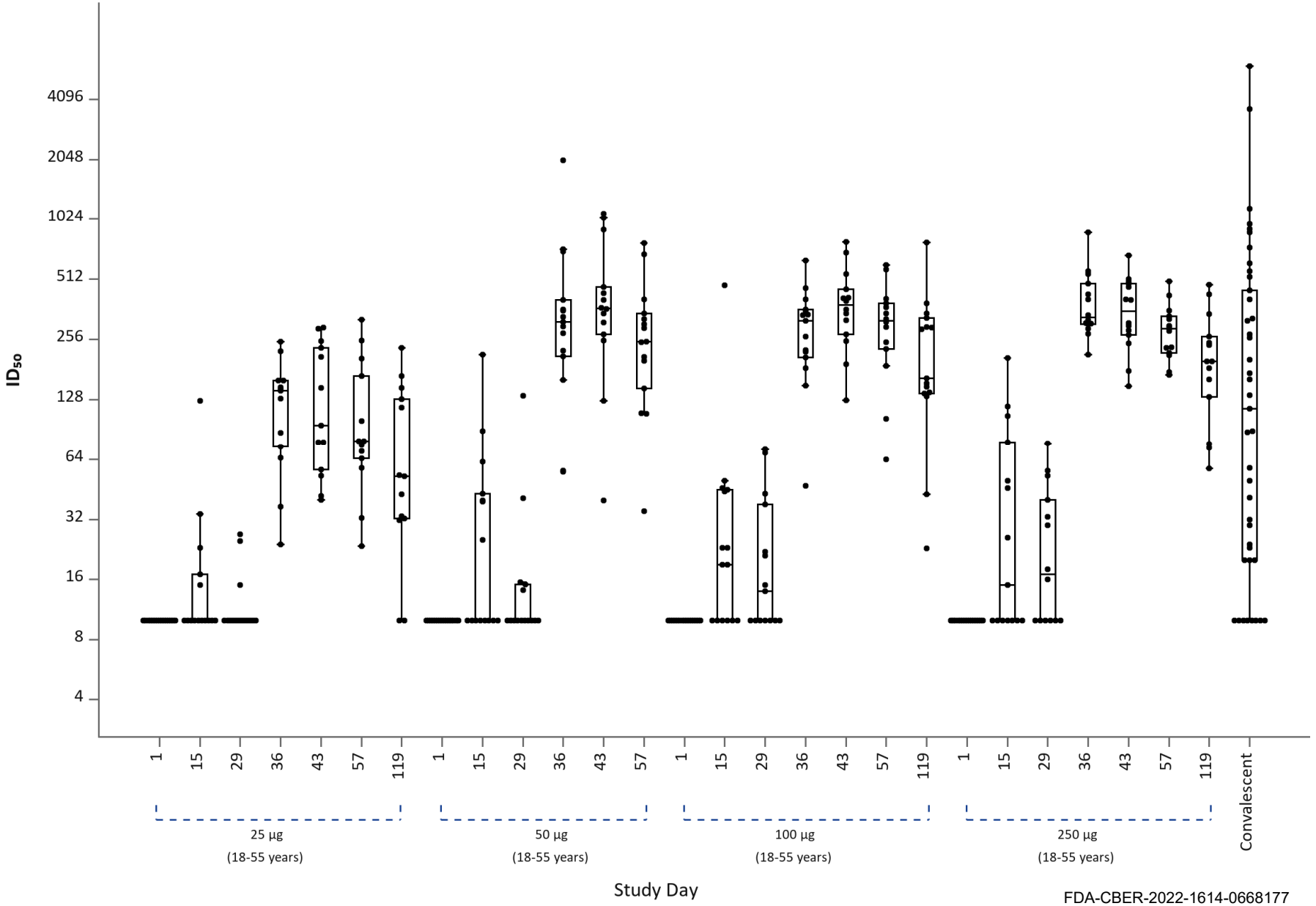


Figure 39: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 56-70, Per Protocol Population

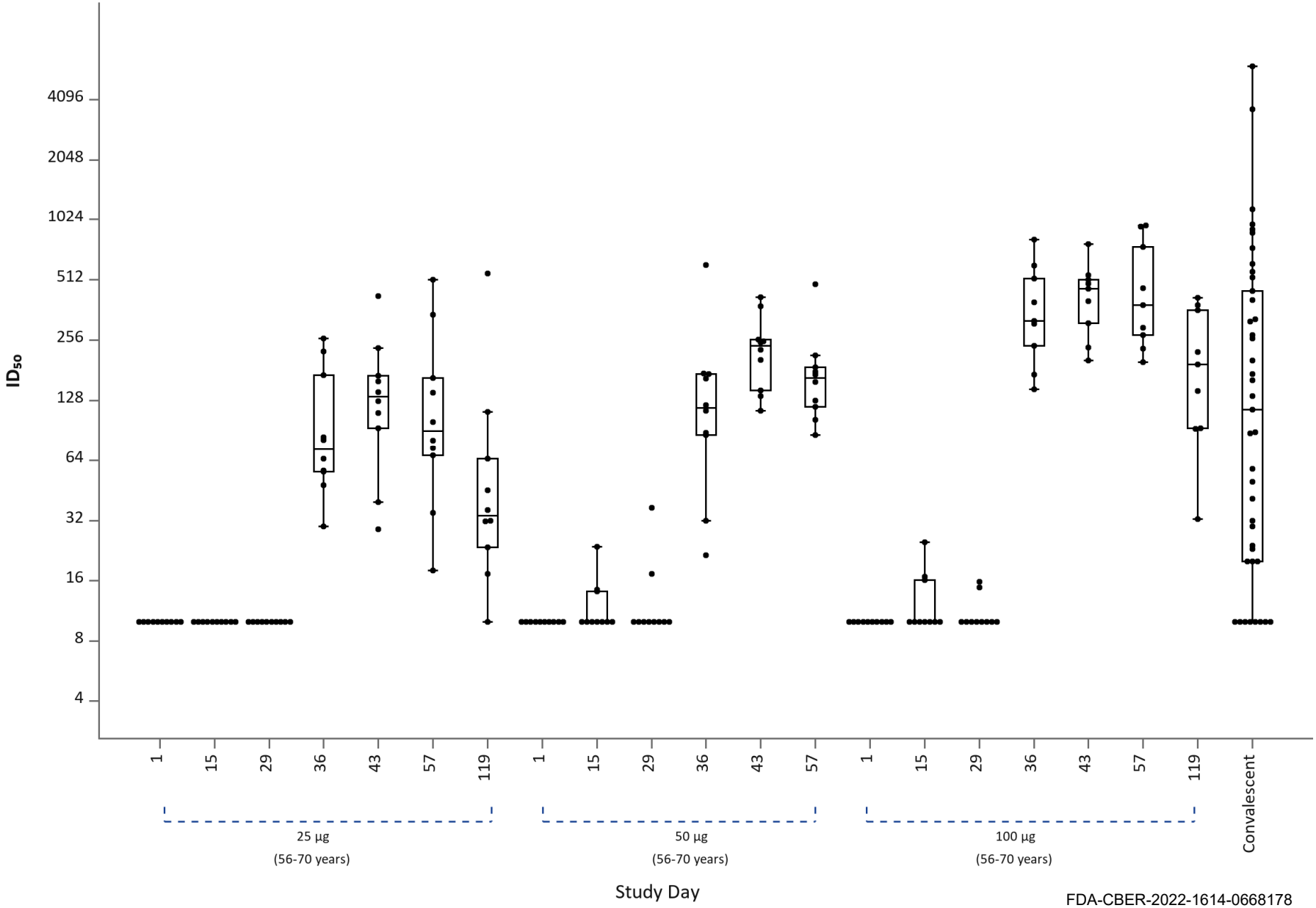


Figure 40: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age ≥71, Per Protocol Population

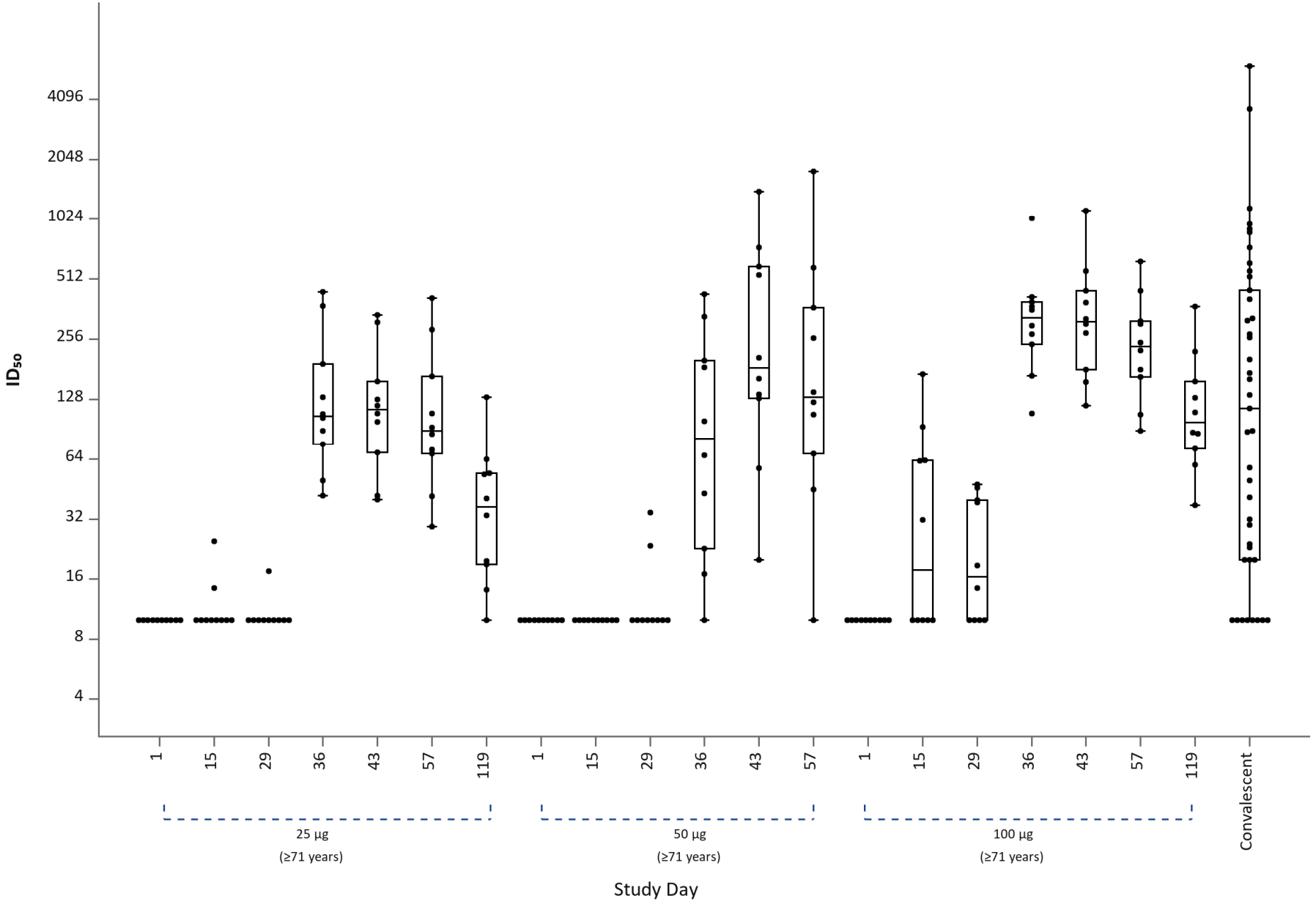


Figure 41: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 18-55, Per Protocol Population

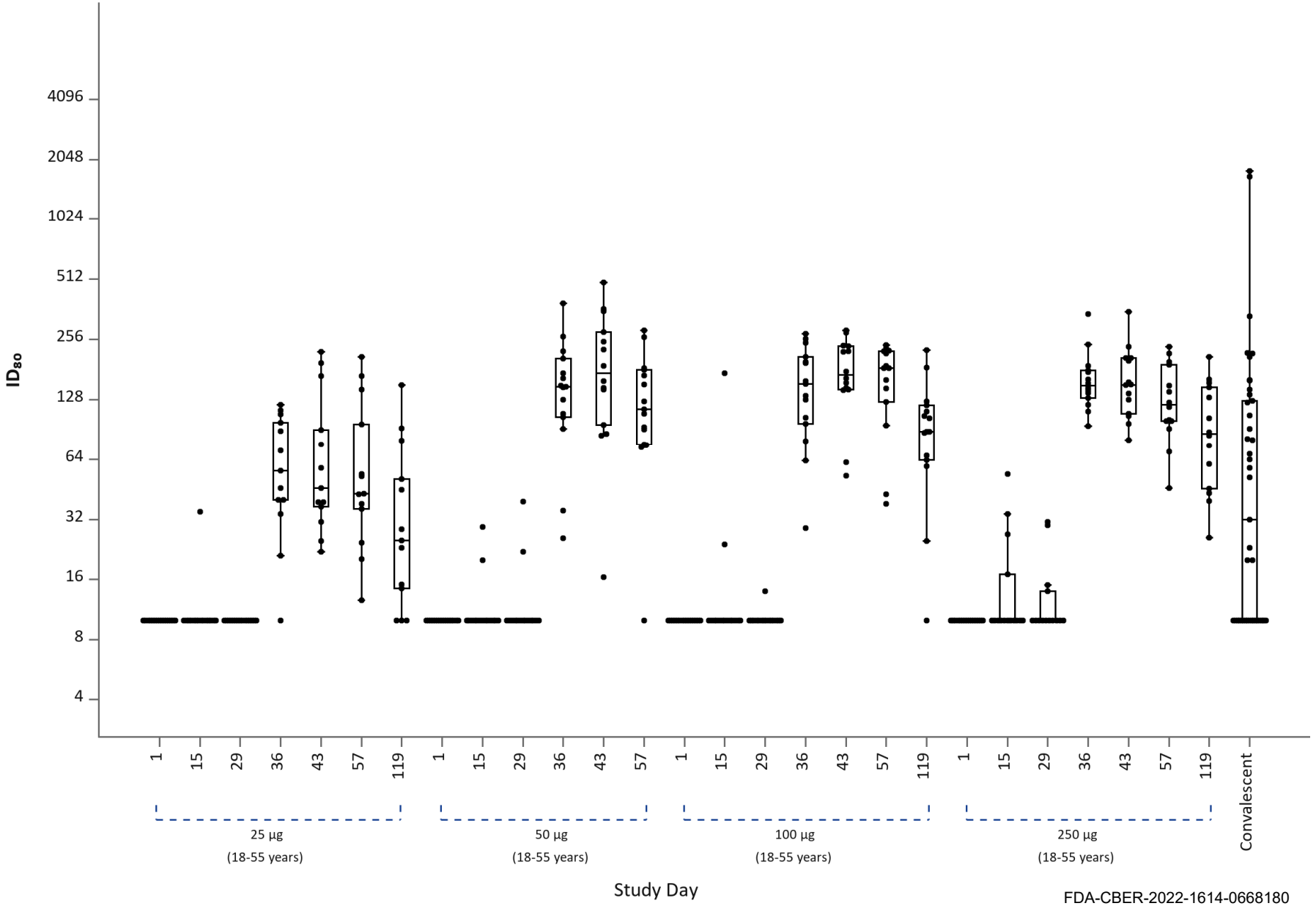


Figure 42: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 56-70, Per Protocol Population

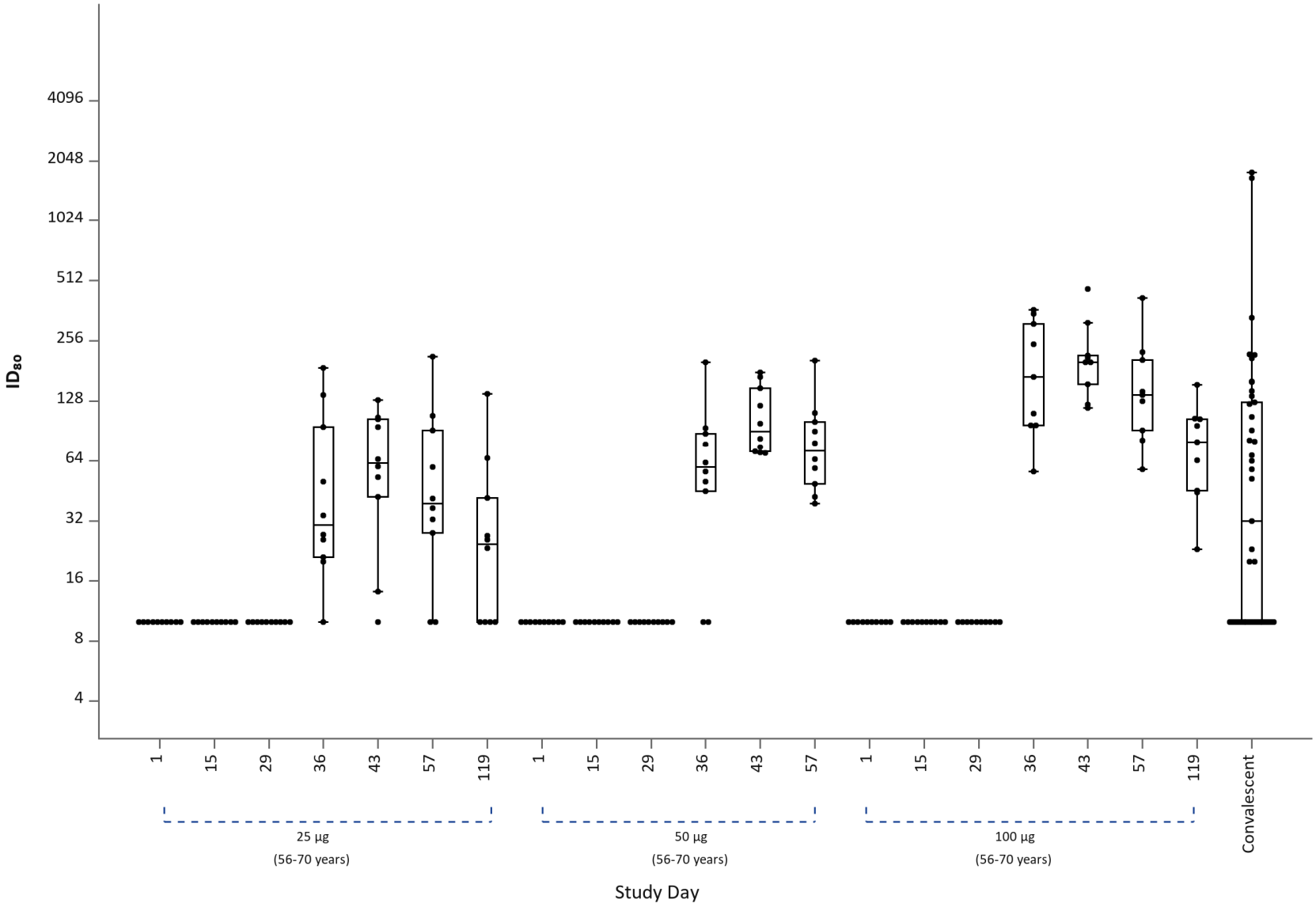


Figure 43: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

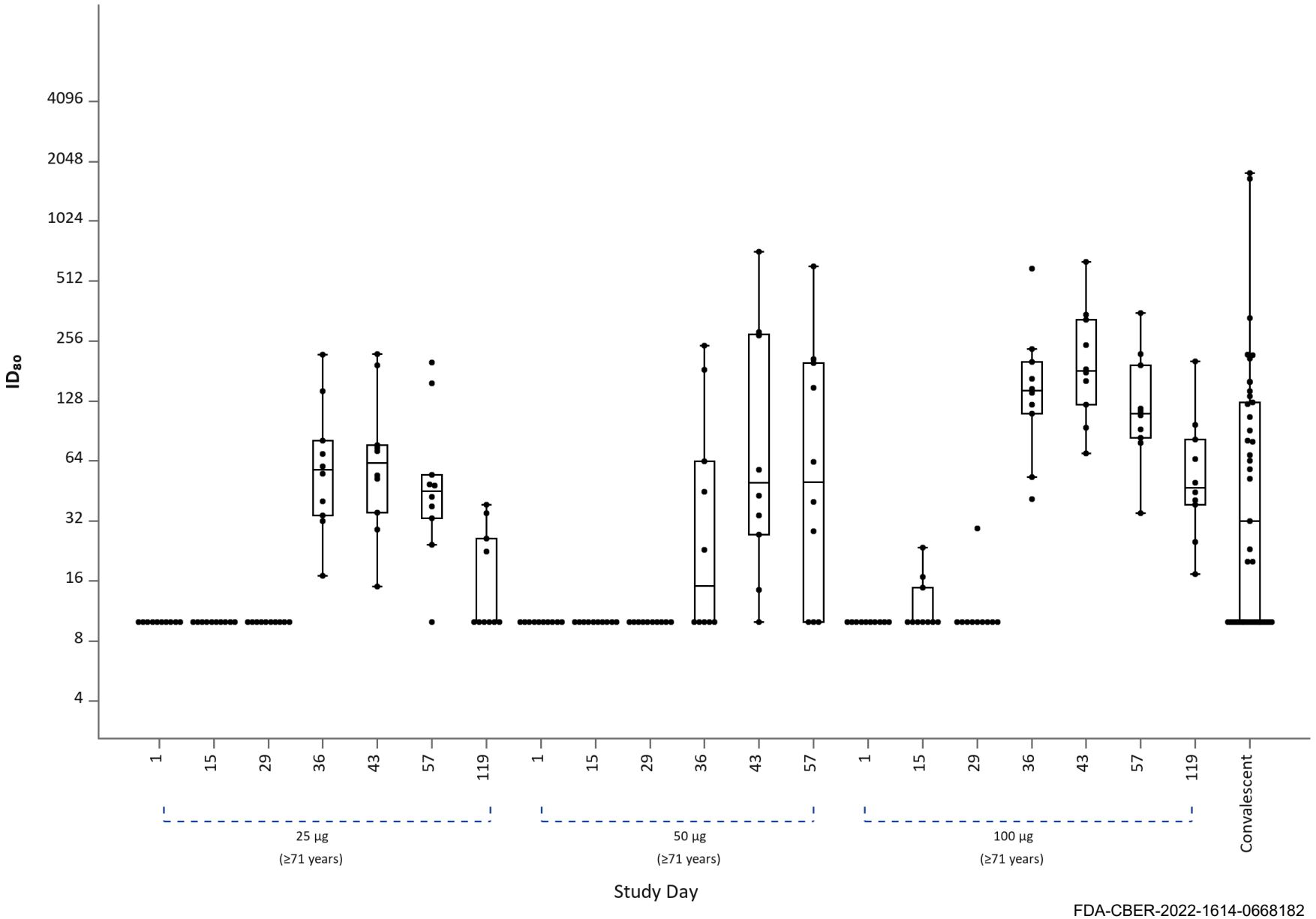


Figure 44: Plaque Reduction Neutralization Test Titers Distribution by Time Point and Treatment Group - $PRNT_{80}$, Per Protocol Population

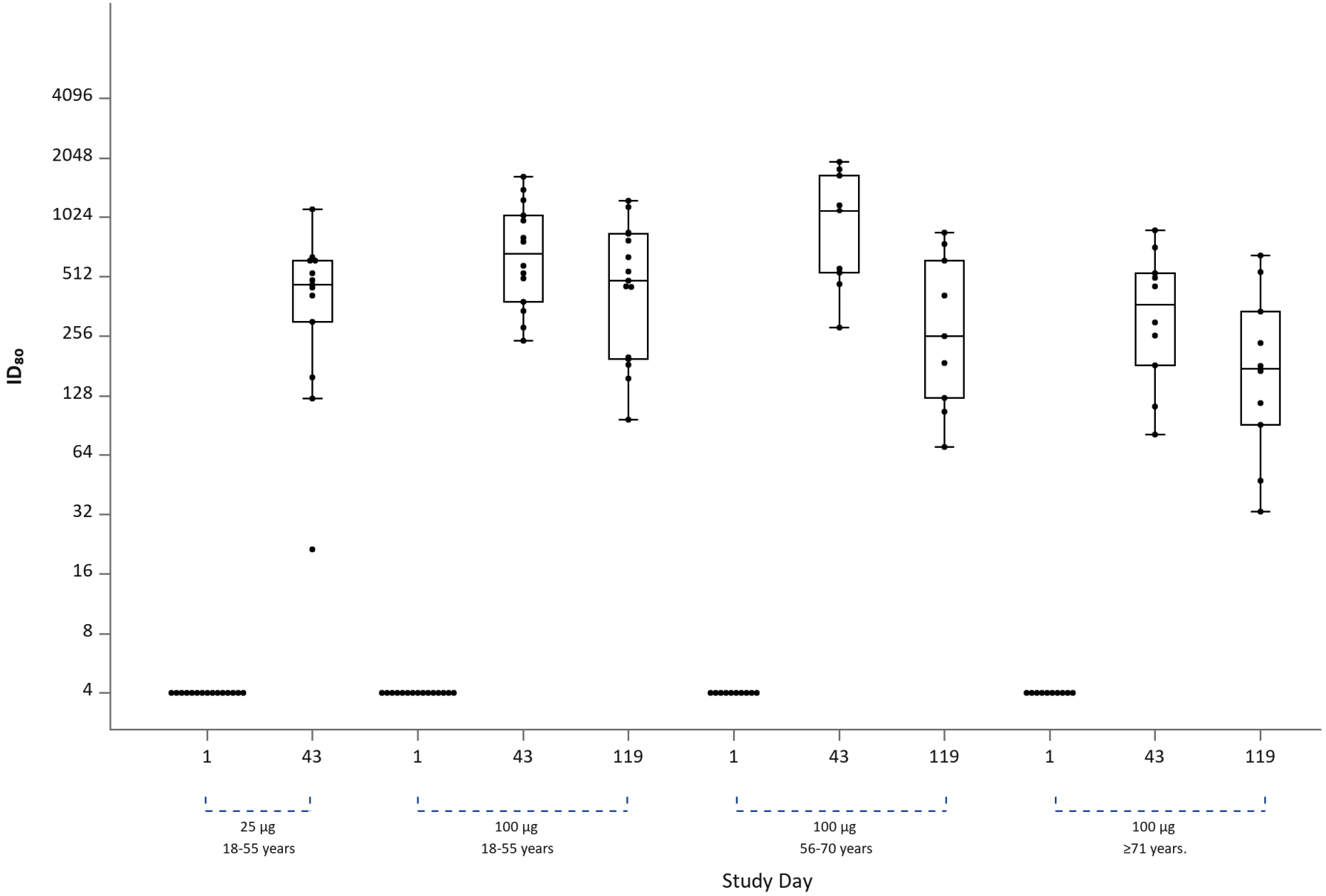


Figure 45: FRNT Titers Distribution by Time Point and Treatment Group - ID_{50}, Per Protocol Population

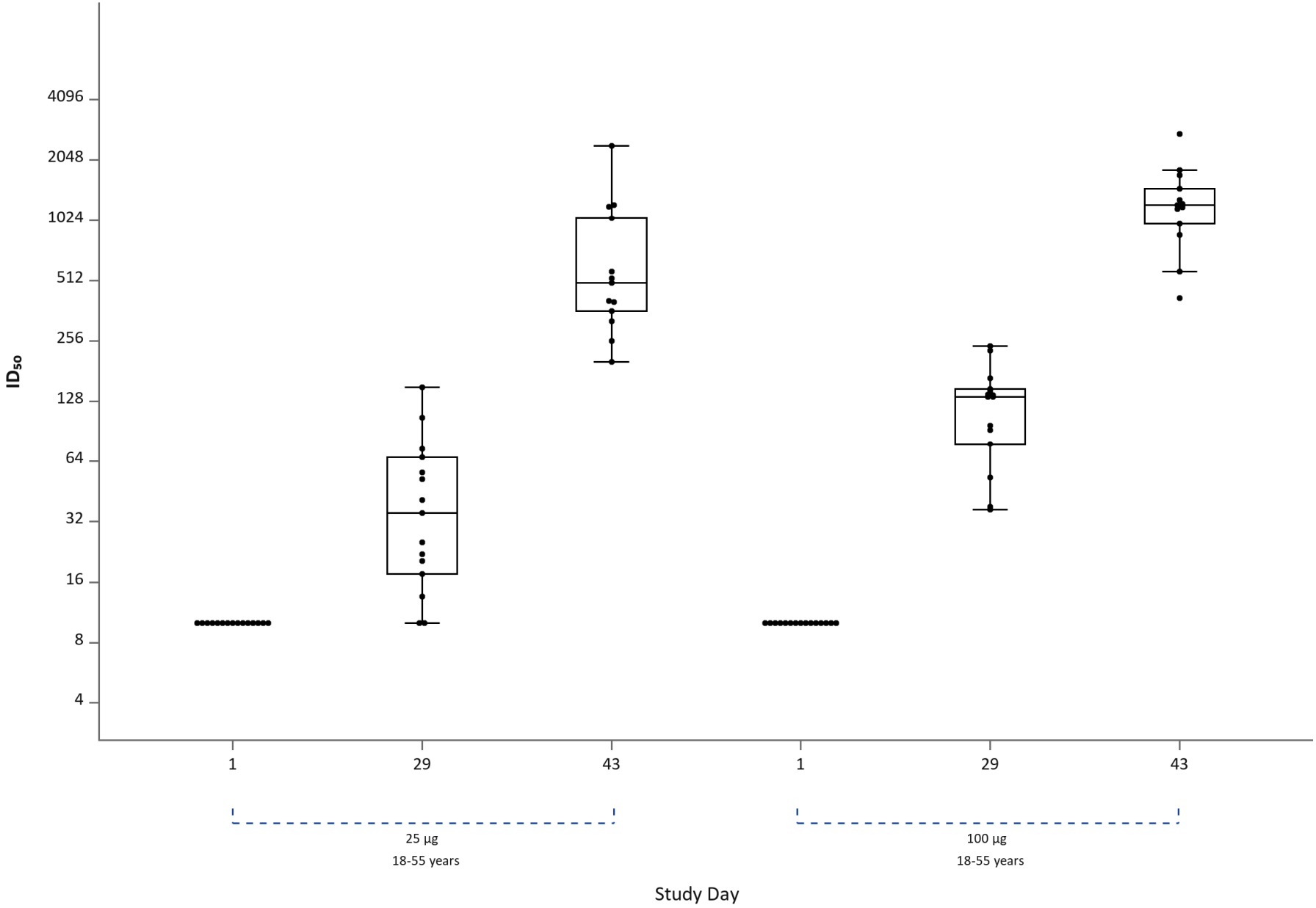


Figure 46: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 18-55, Per Protocol Population

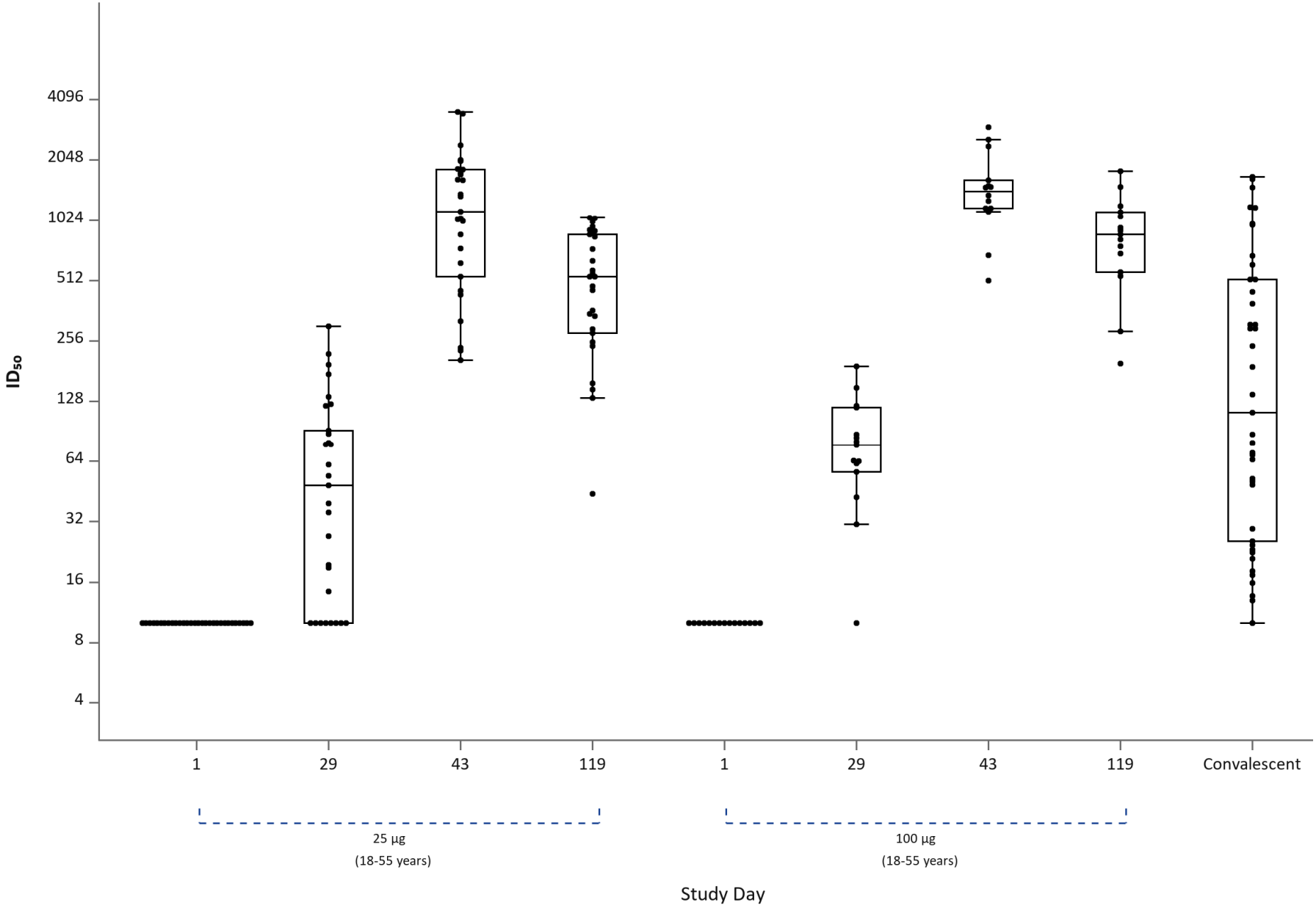


Figure 47: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 56-70, Per Protocol Population

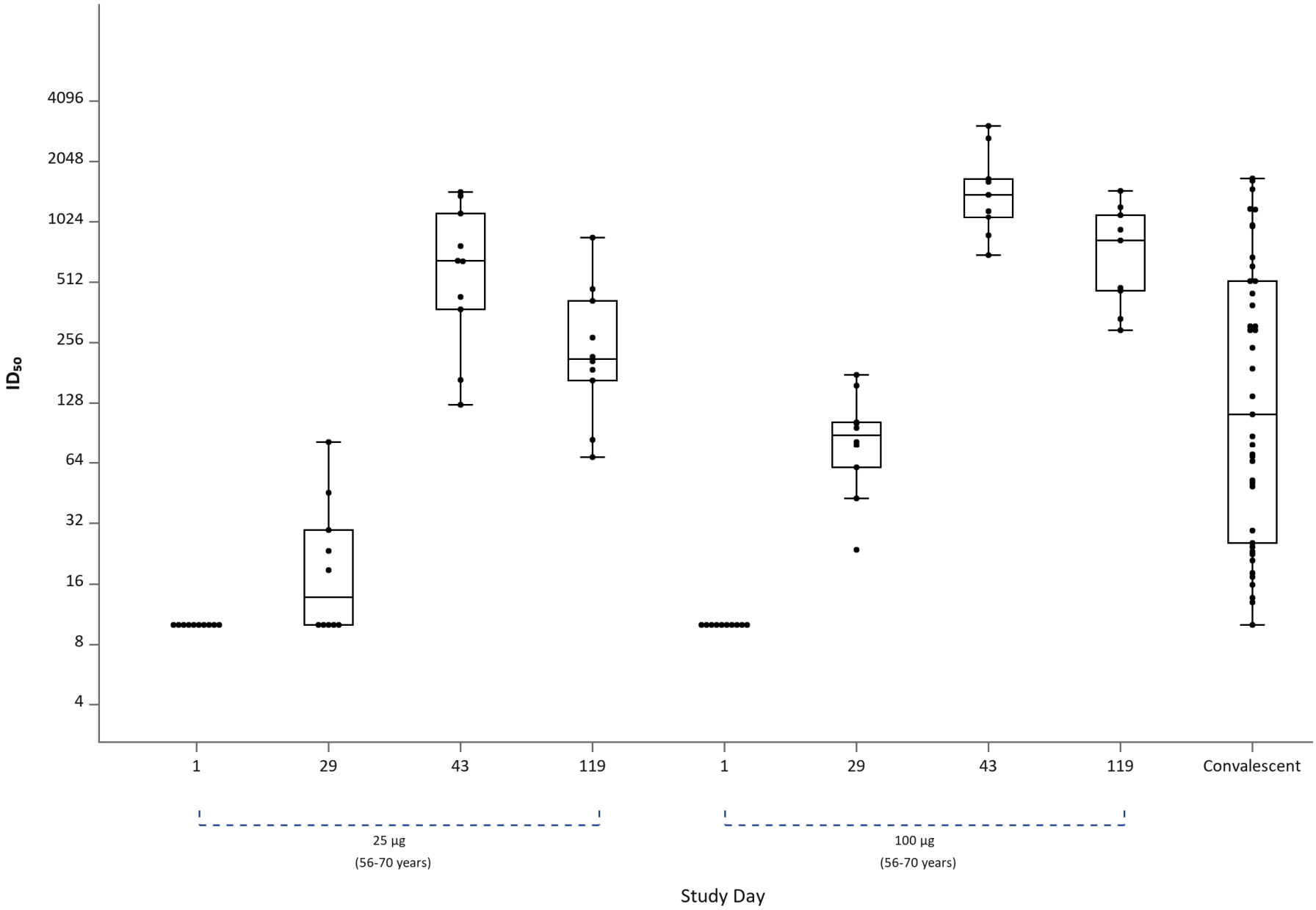


Figure 48: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age ≥71, Per Protocol Population

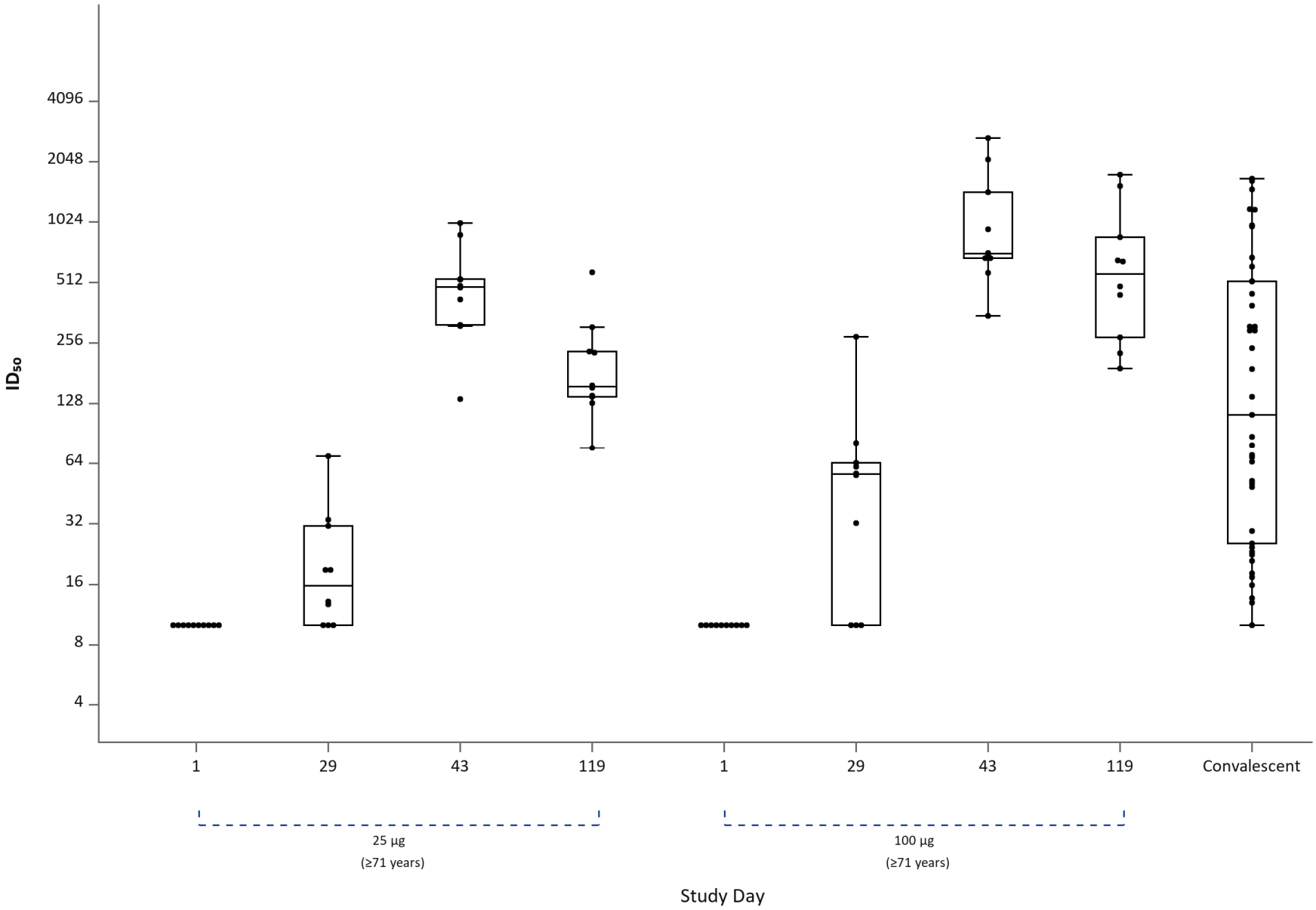


Figure 49: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 18-55, Per Protocol Population

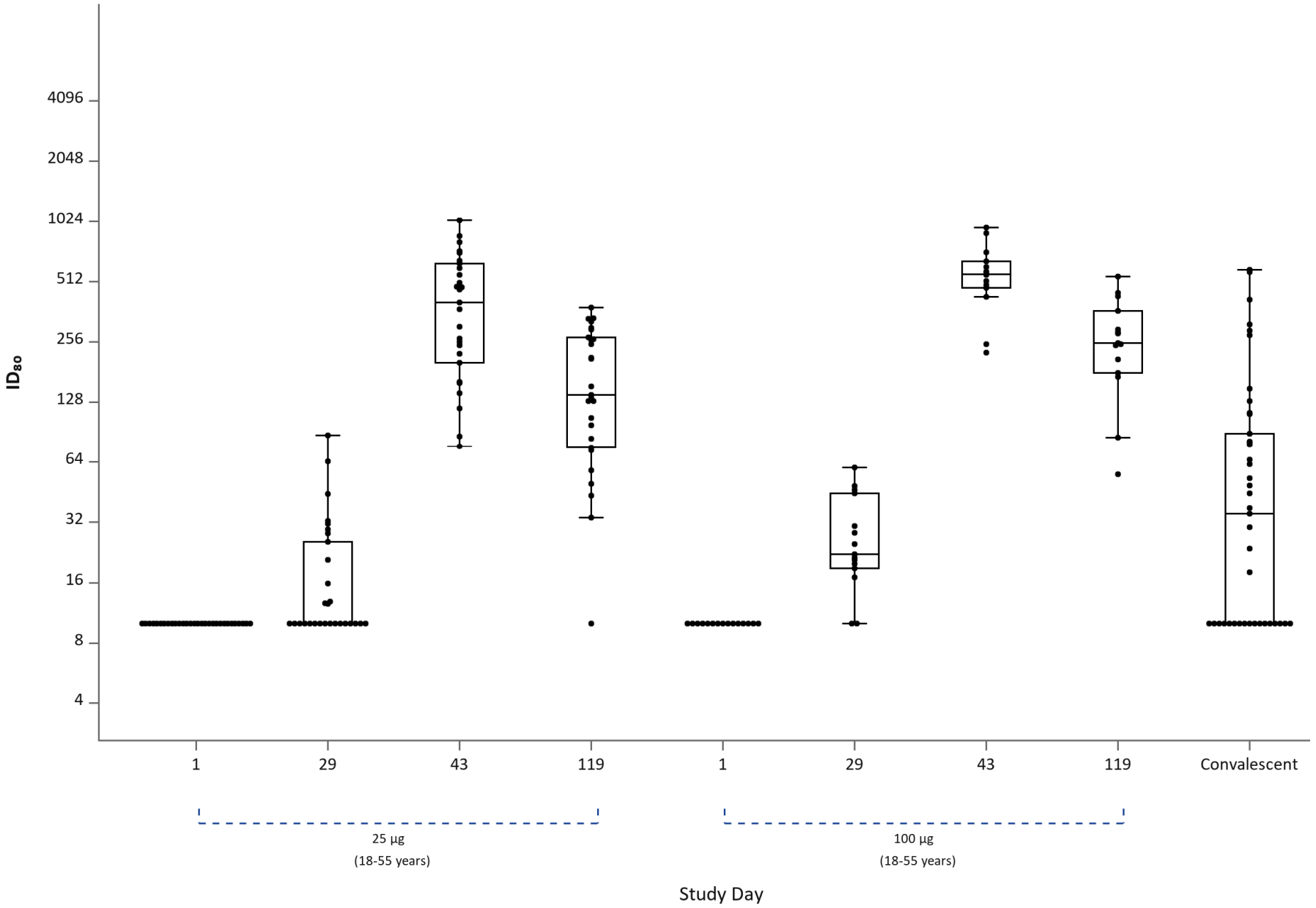


Figure 50: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 56-70, Per Protocol Population

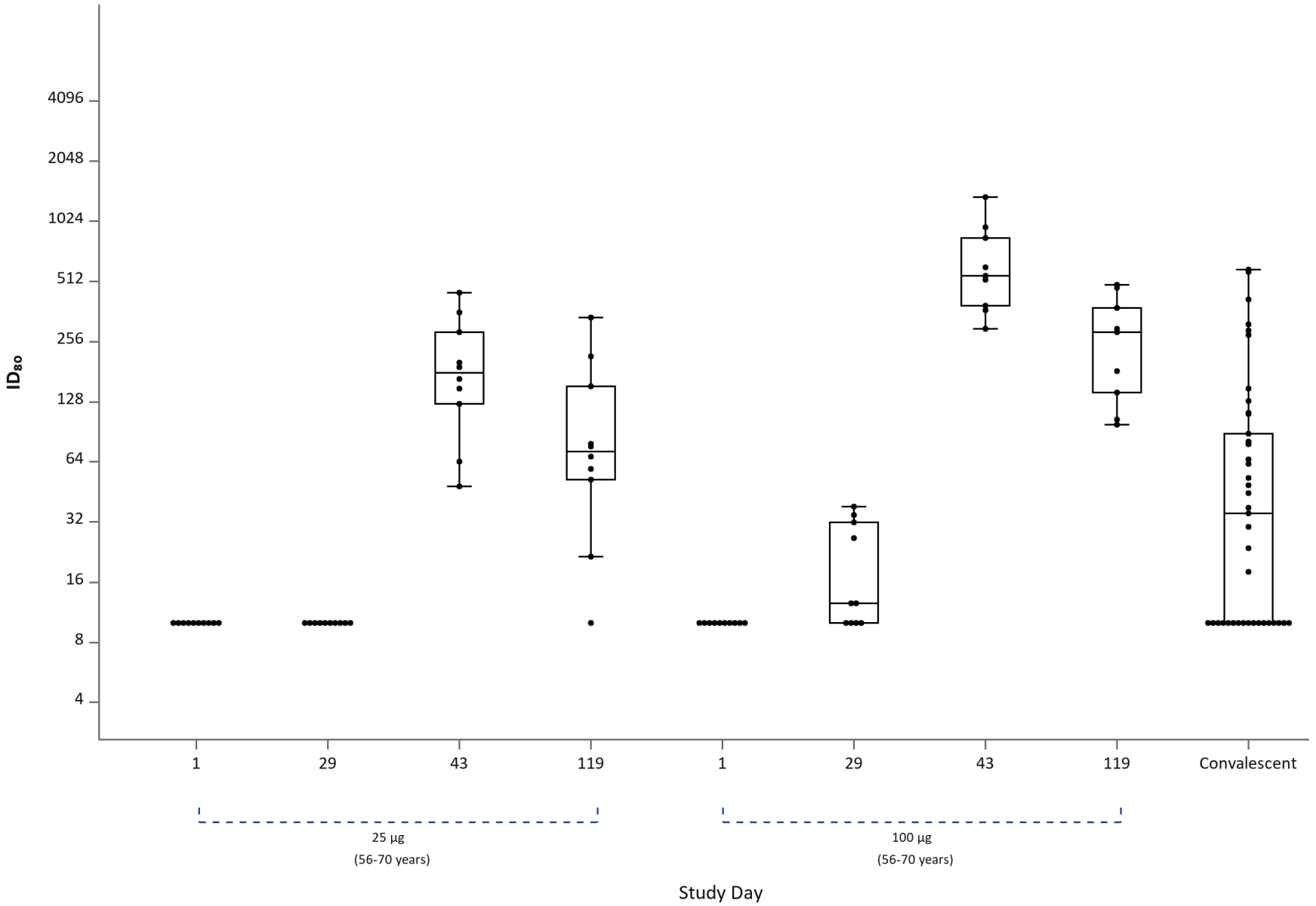


Figure 51: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

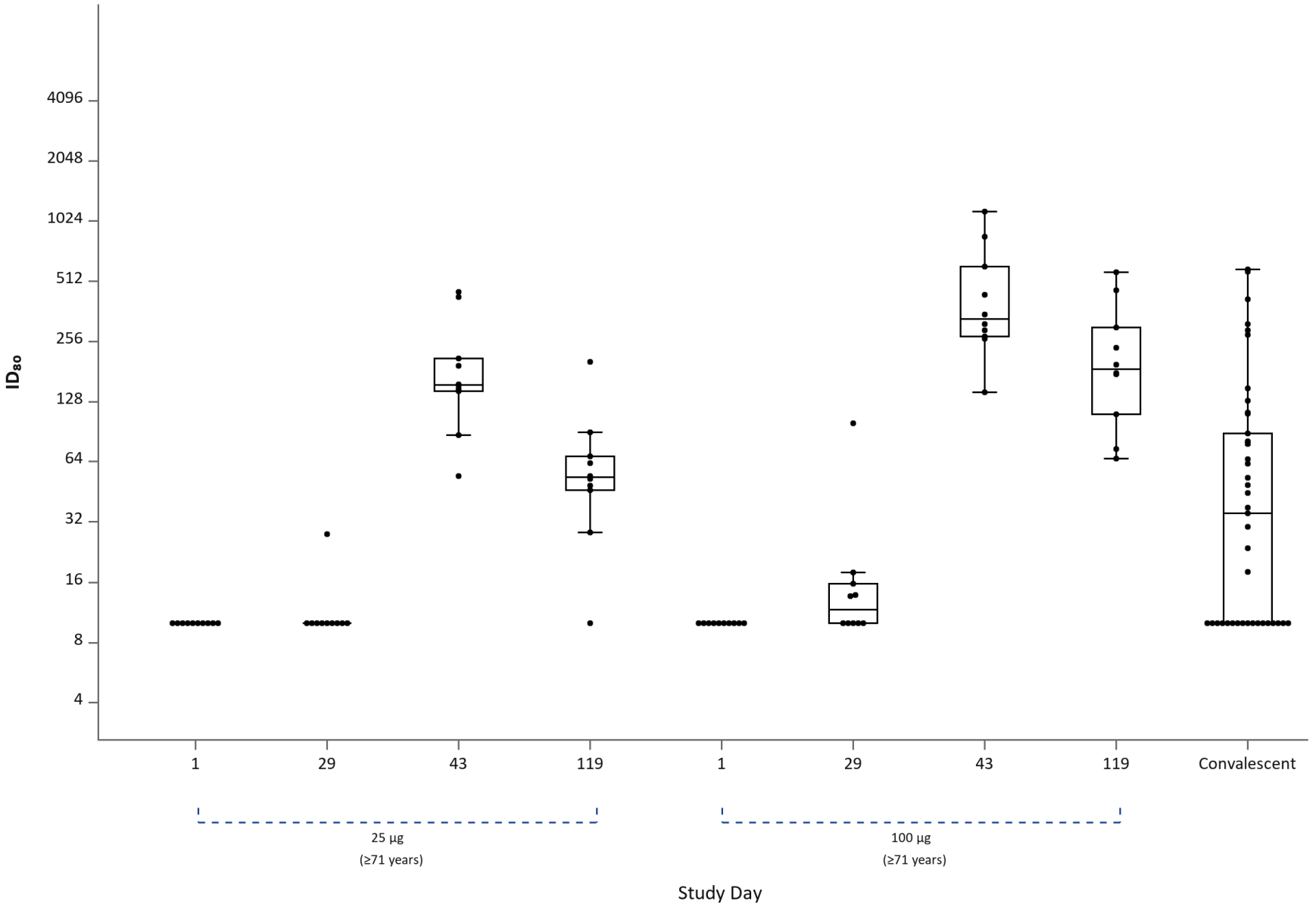


Figure 52: nLuciferase Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50}, Per Protocol Population

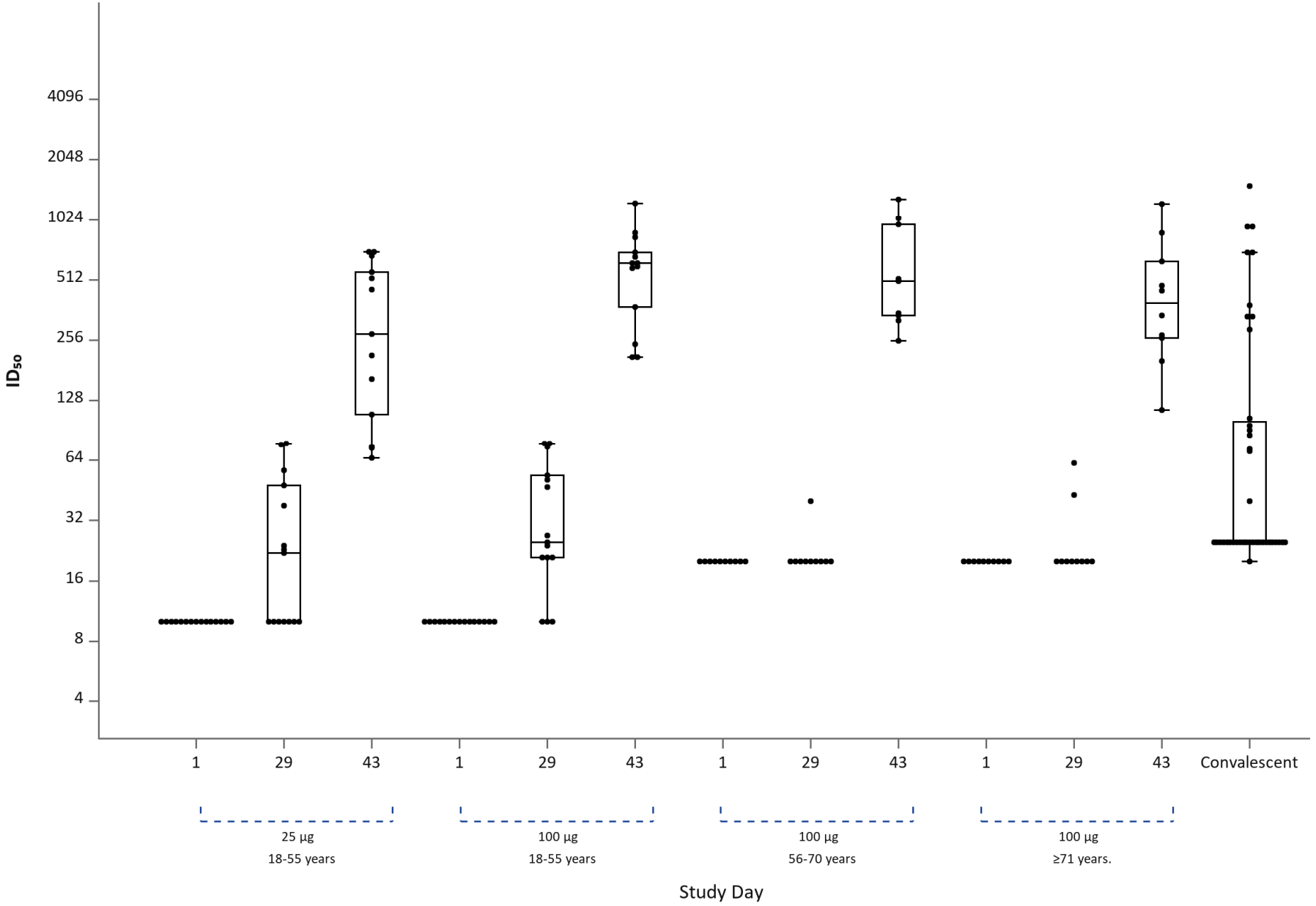


Figure 53: nLuciferase Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80}, Per Protocol Population

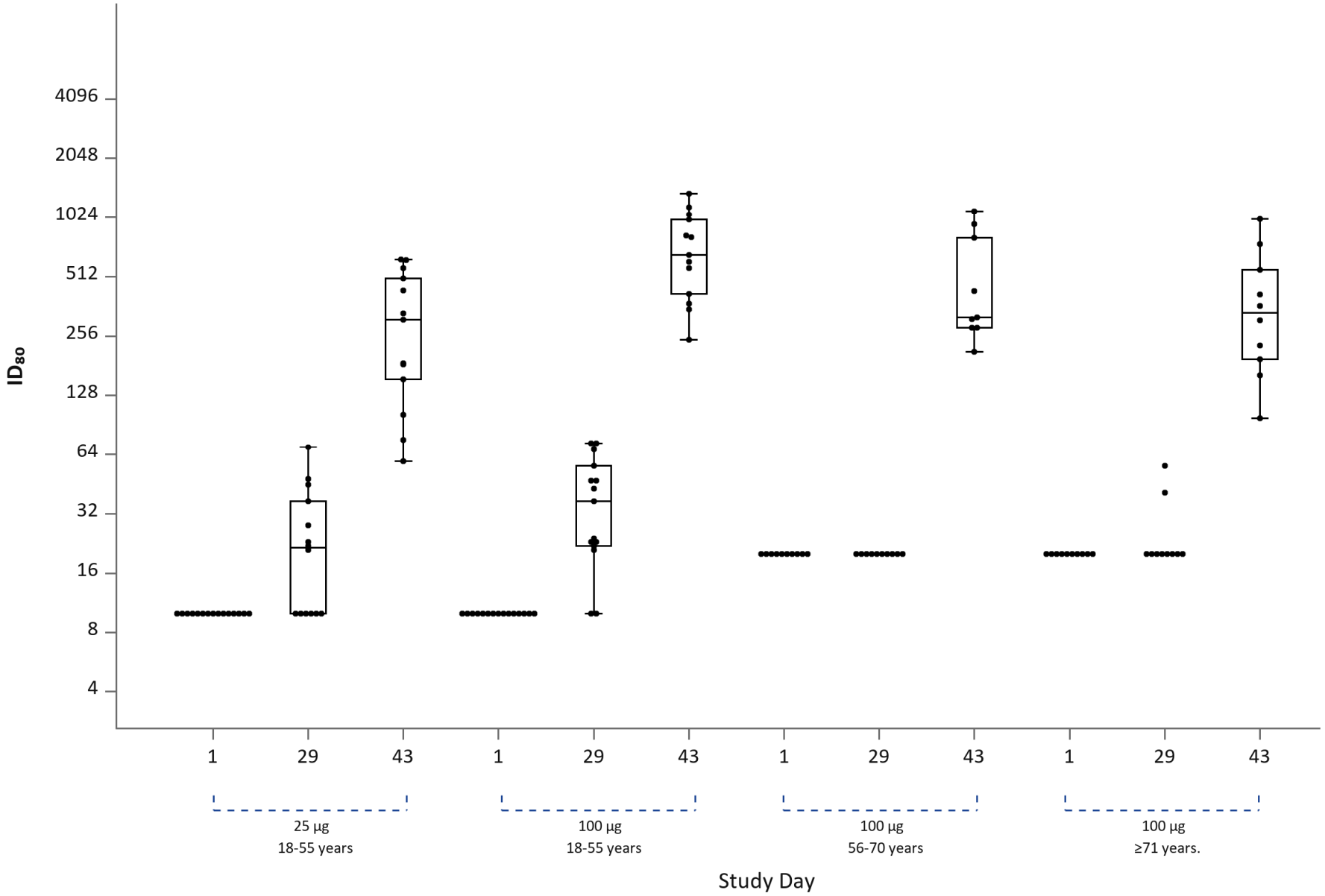
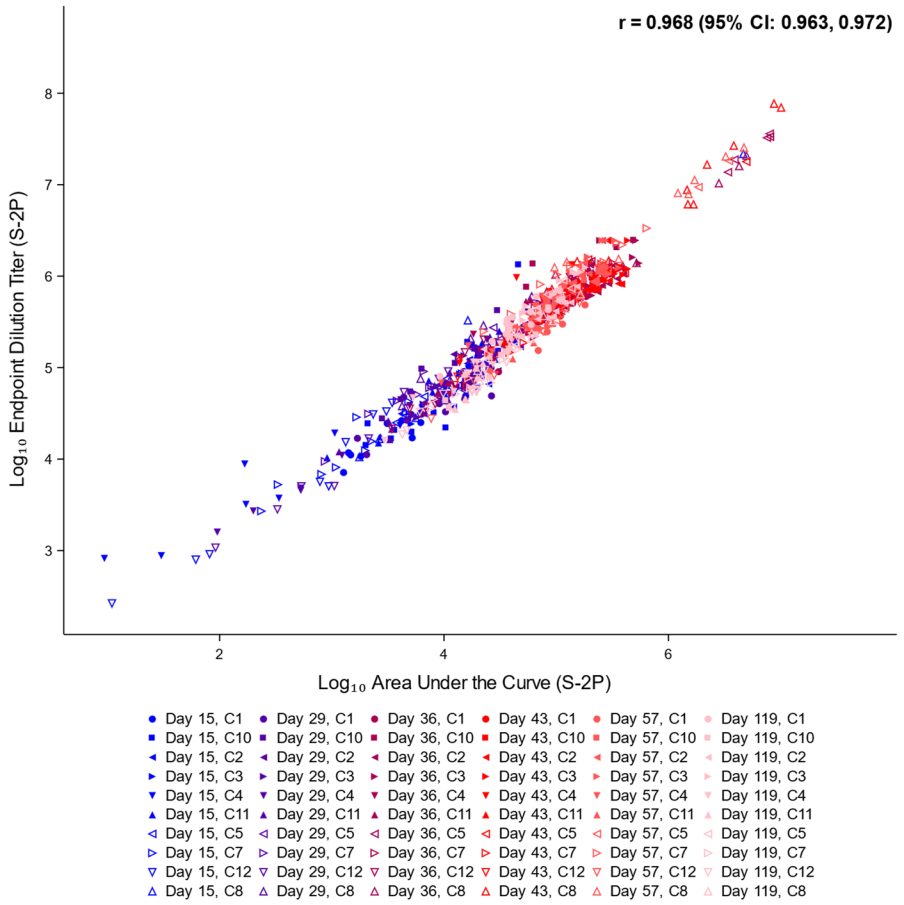


Figure 54: Binding to SARS-CoV-2 Spike Proteins in ELISA Expressed as Area-Under-the-Curve (AUC) is Highly Correlated with Binding Expressed as Endpoint Dilution Titer, Per Protocol Population

A, vaccinee sera binding to S-2P expressed as endpoint vs AUC. **B**, vaccinee sera binding to RBD expressed as endpoint vs AUC.
C, convalescent sera binding to S-2P expressed as endpoint vs AUC. **D**, convalescent sera binding to RBD expressed as endpoint vs AUC.

A



B

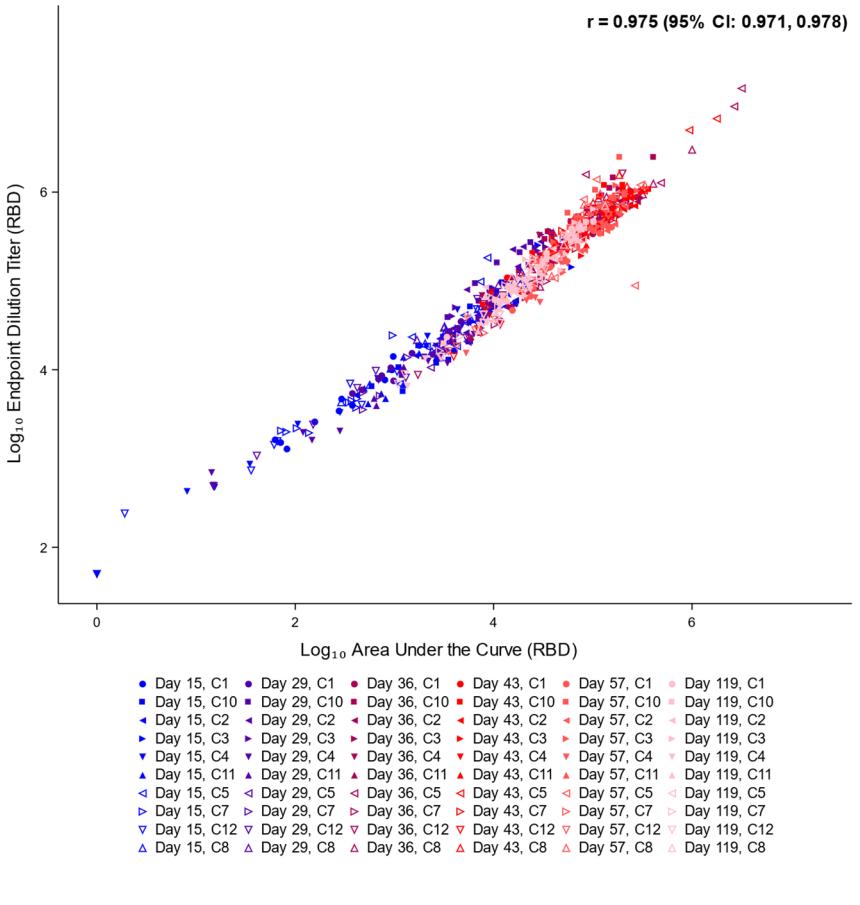
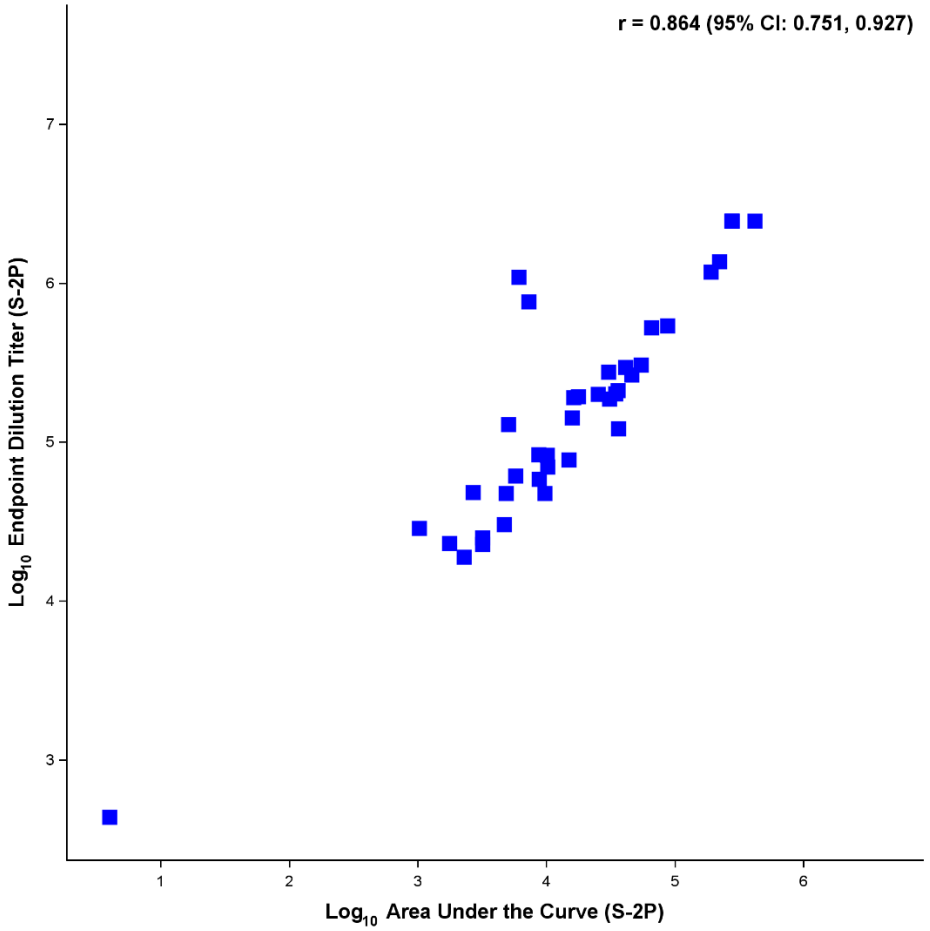


Figure 54 (continued)

C



D

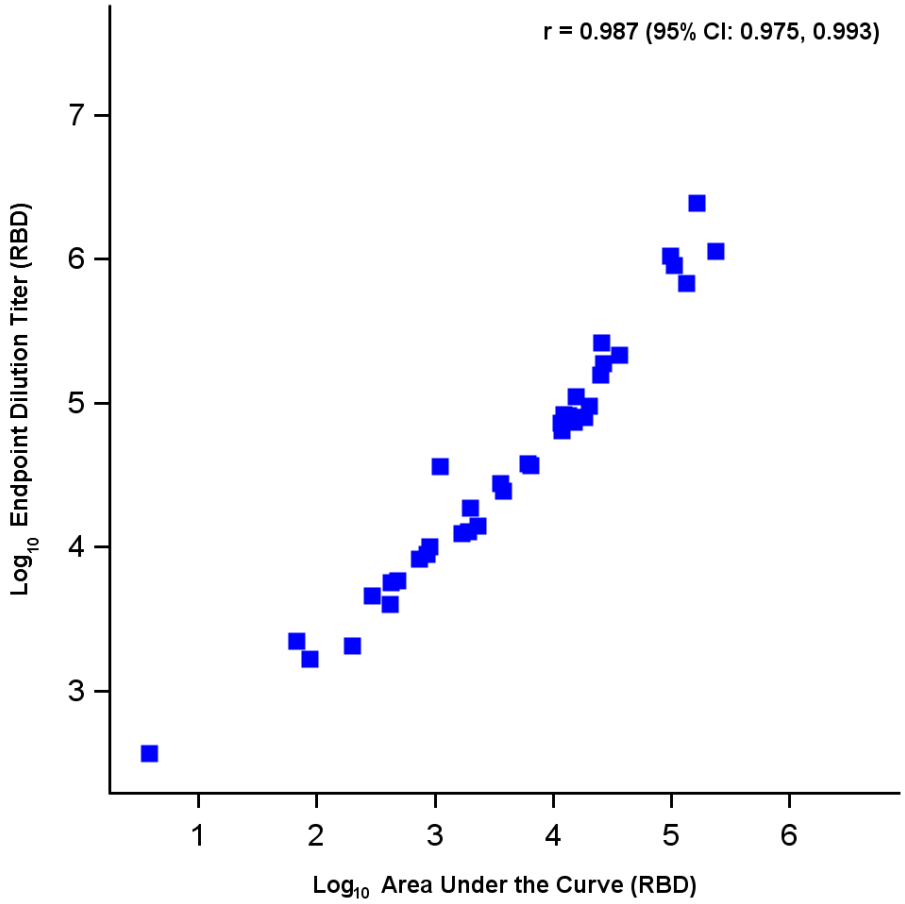
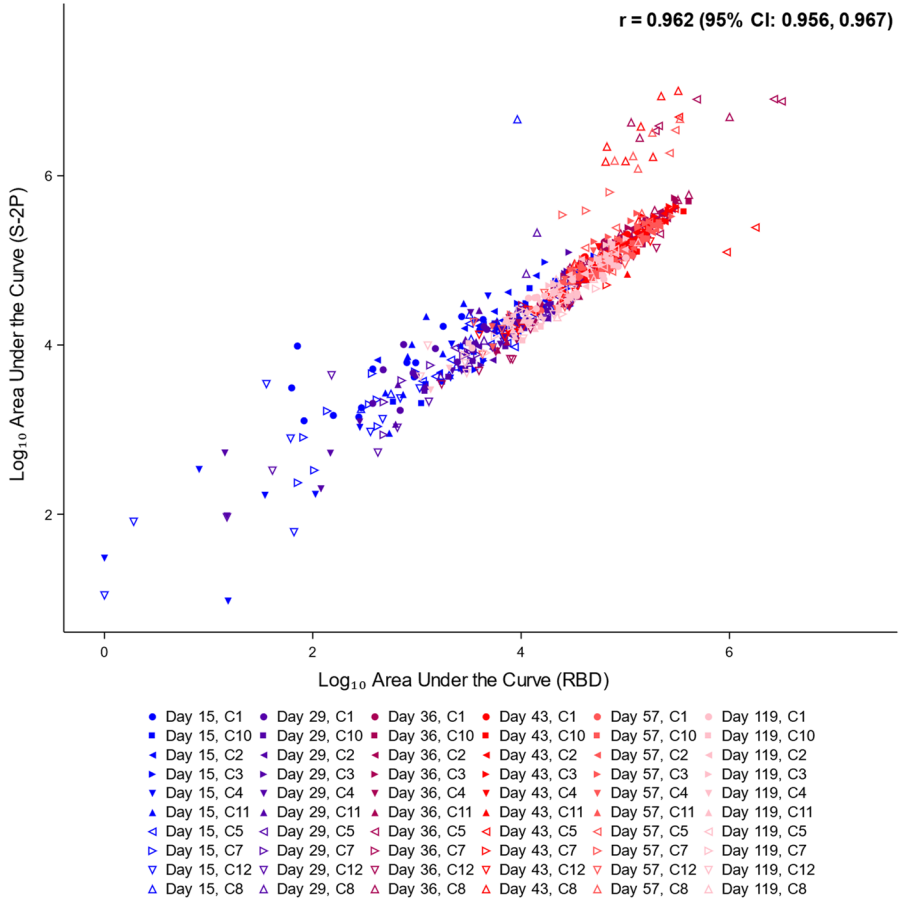


Figure 55: Binding to S-2P or RBD Proteins are Highly Correlated, Per Protocol Population

A, vaccinee sera binding to S-2P vs. RBD, expressed as area under the curve (AUC). **B**, vaccinee sera binding to S-2P vs. RBD, expressed as endpoint dilution titer.
C, convalescent sera binding to S-2P vs. RBD, expressed as AUC. **D**, convalescent sera binding to S-2P vs. RBD, expressed as endpoint dilution titer.

A



B

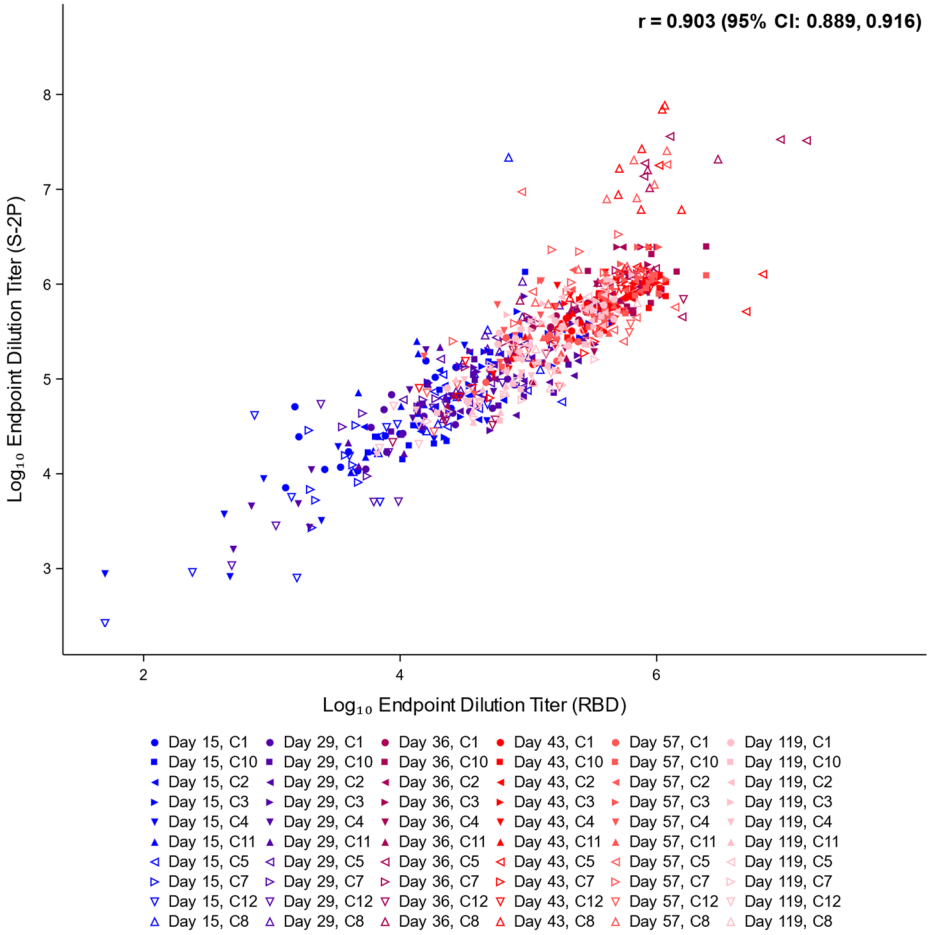
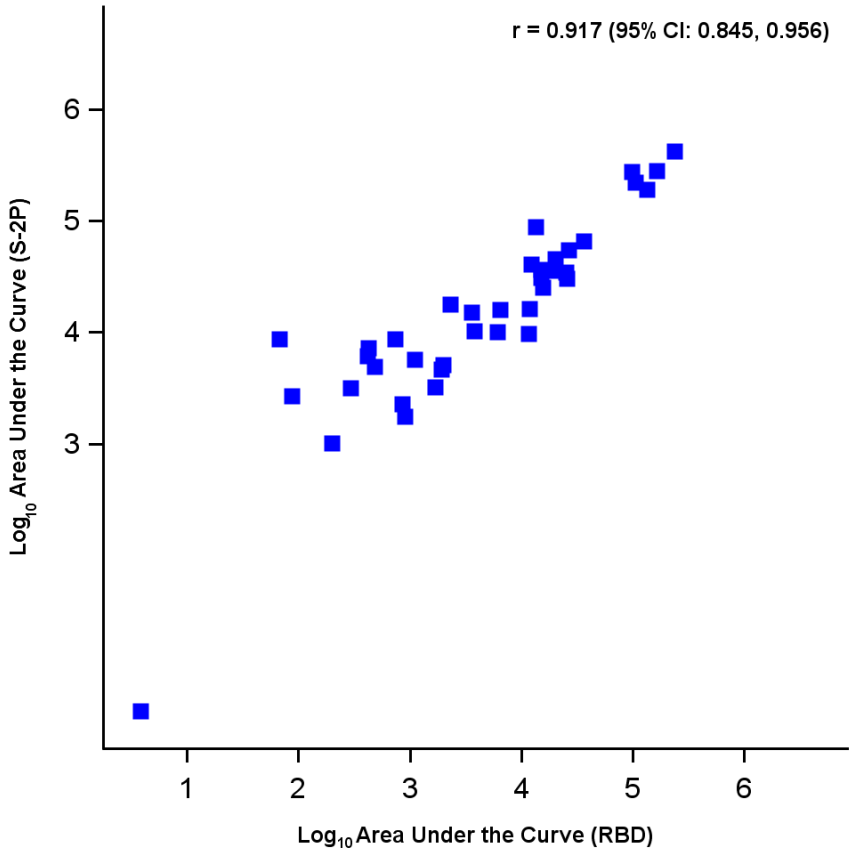


Figure 55 (continued)

C



D

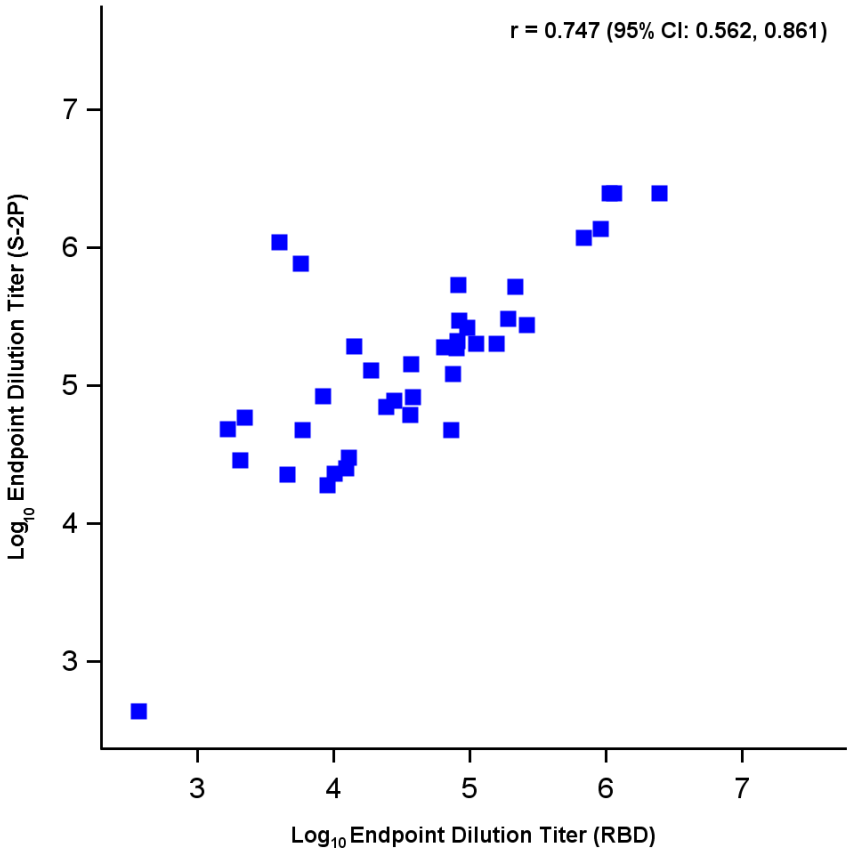
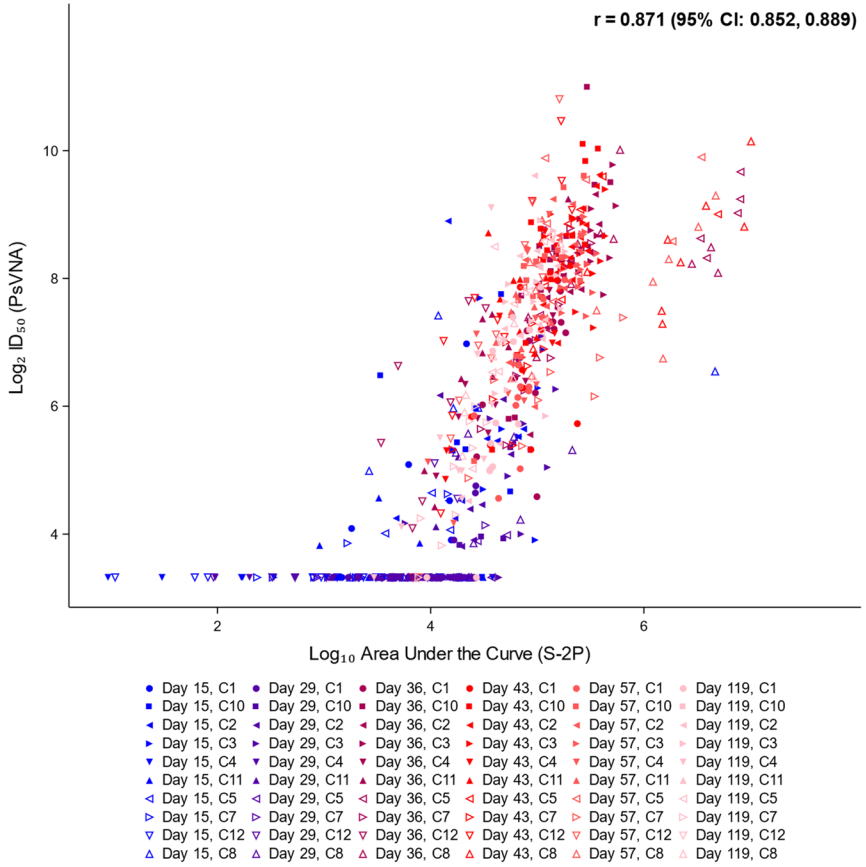


Figure 56: Pseudovirus Neutralization Correlates with Binding in ELISA, Per Protocol Population

A, PsVNA vaccinee sera ID_{50} vs. AUC S2P. **B**, PsVNA vaccinee sera ID_{80} vs. AUC S2P. **C**, PsVNA convalescent sera ID_{50} vs. AUC S2P. **D**, PsVNAconvalescent sera ID_{80} vs. AUC S2P

A



B

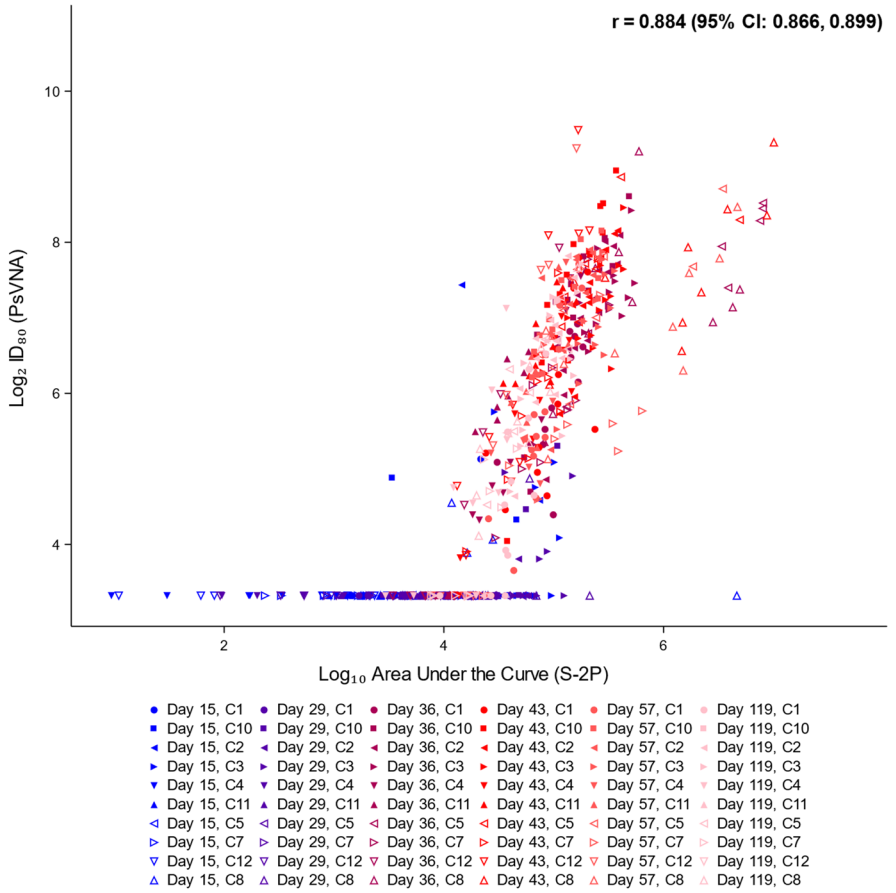
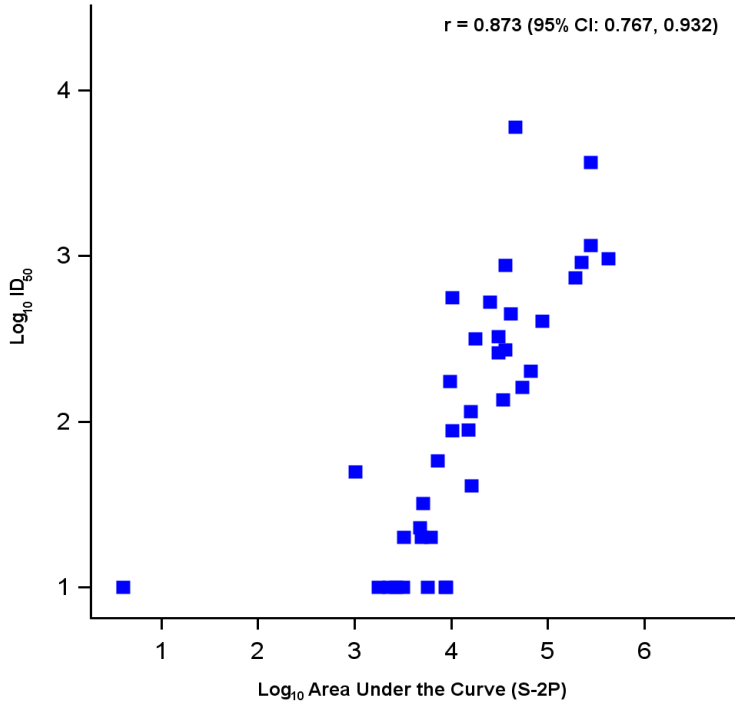


Figure 56 (continued)

C



D

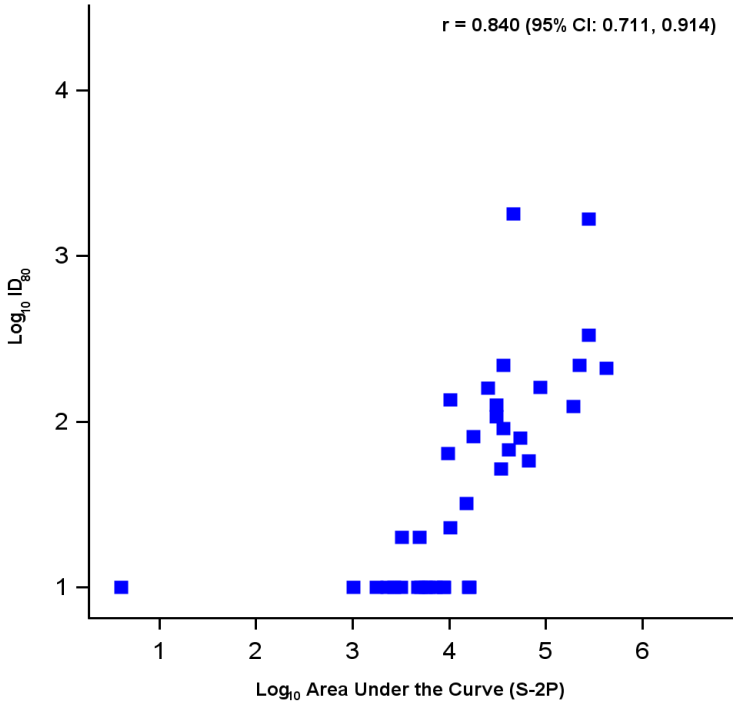
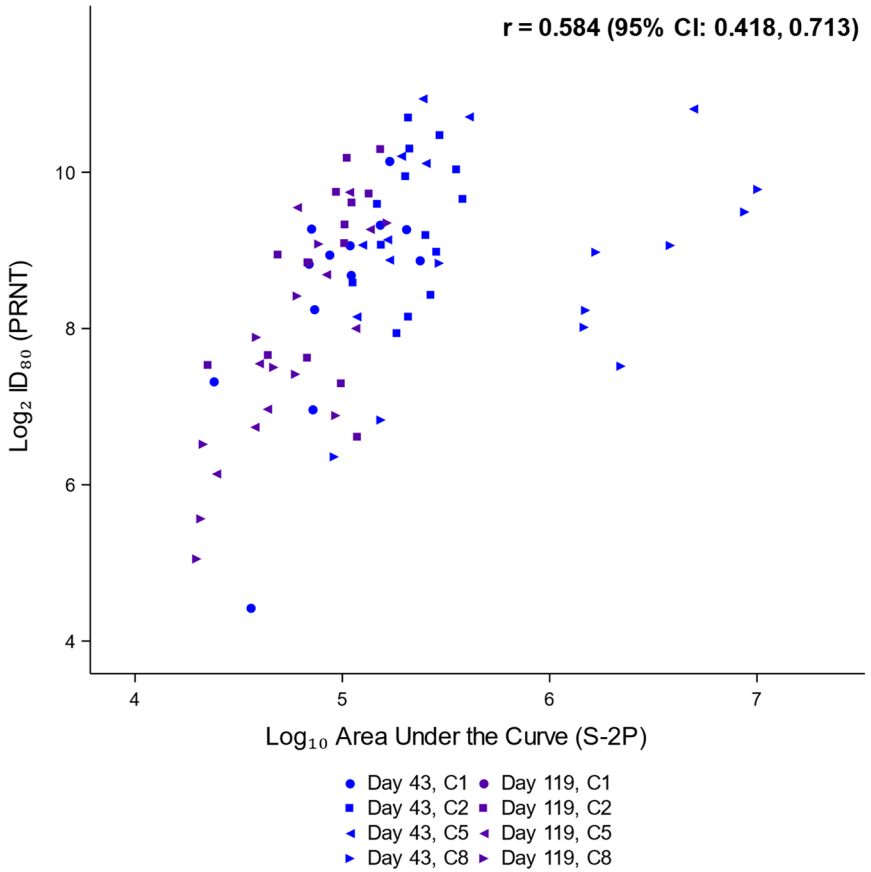


Figure 57: Live-Virus Neutralization (PRNT80) Correlates with Binding in ELISA, Per Protocol Population

A, $PRNT_{80}$ vs. S-2P binding (AUC) . **B**, $PRNT_{80}$ vs. RBD binding (AUC).

A



B

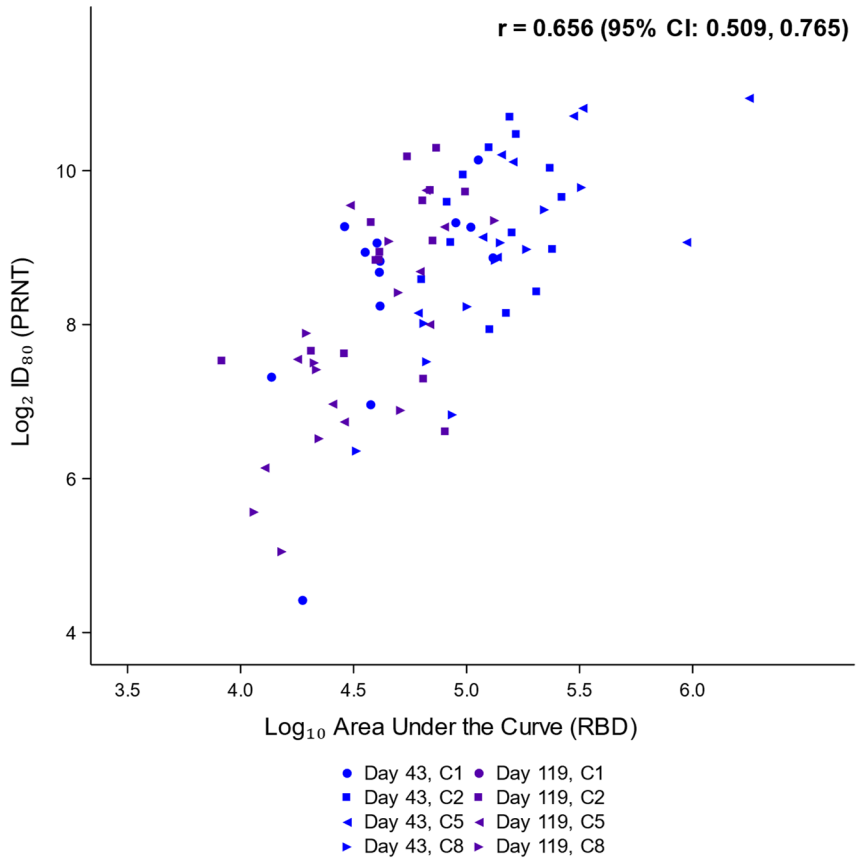
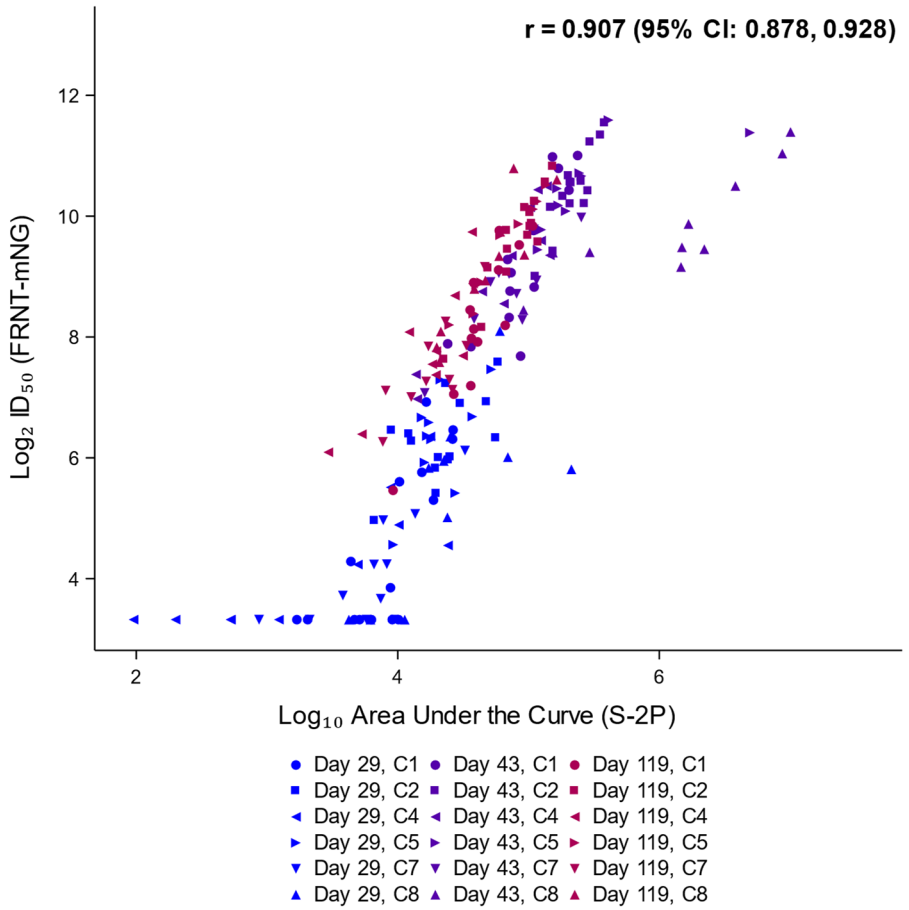


Figure 58: FRNT-mNG Correlates with Binding in ELISA, Per Protocol Population

A,.FRNT50 vs. S-2P binding (AUC) ; **B**, FRNT50 vs. RBD binding (AUC).

A



B

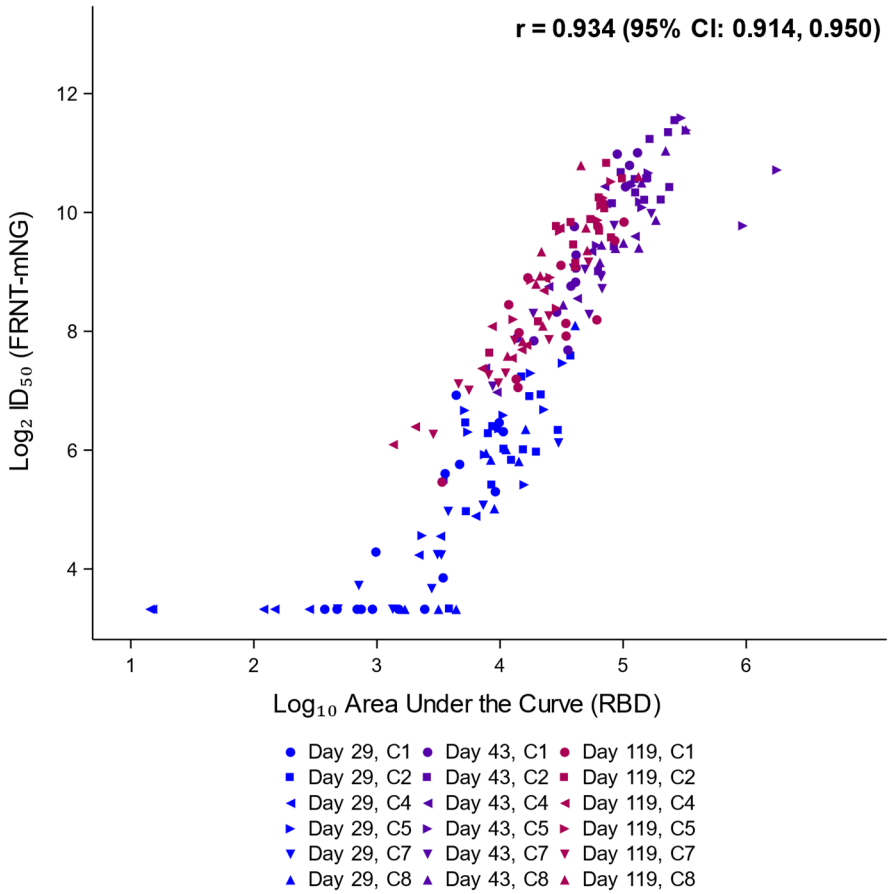


Figure 59: Correlation Heatmap, Per Protocol Population - Per Protocol Population

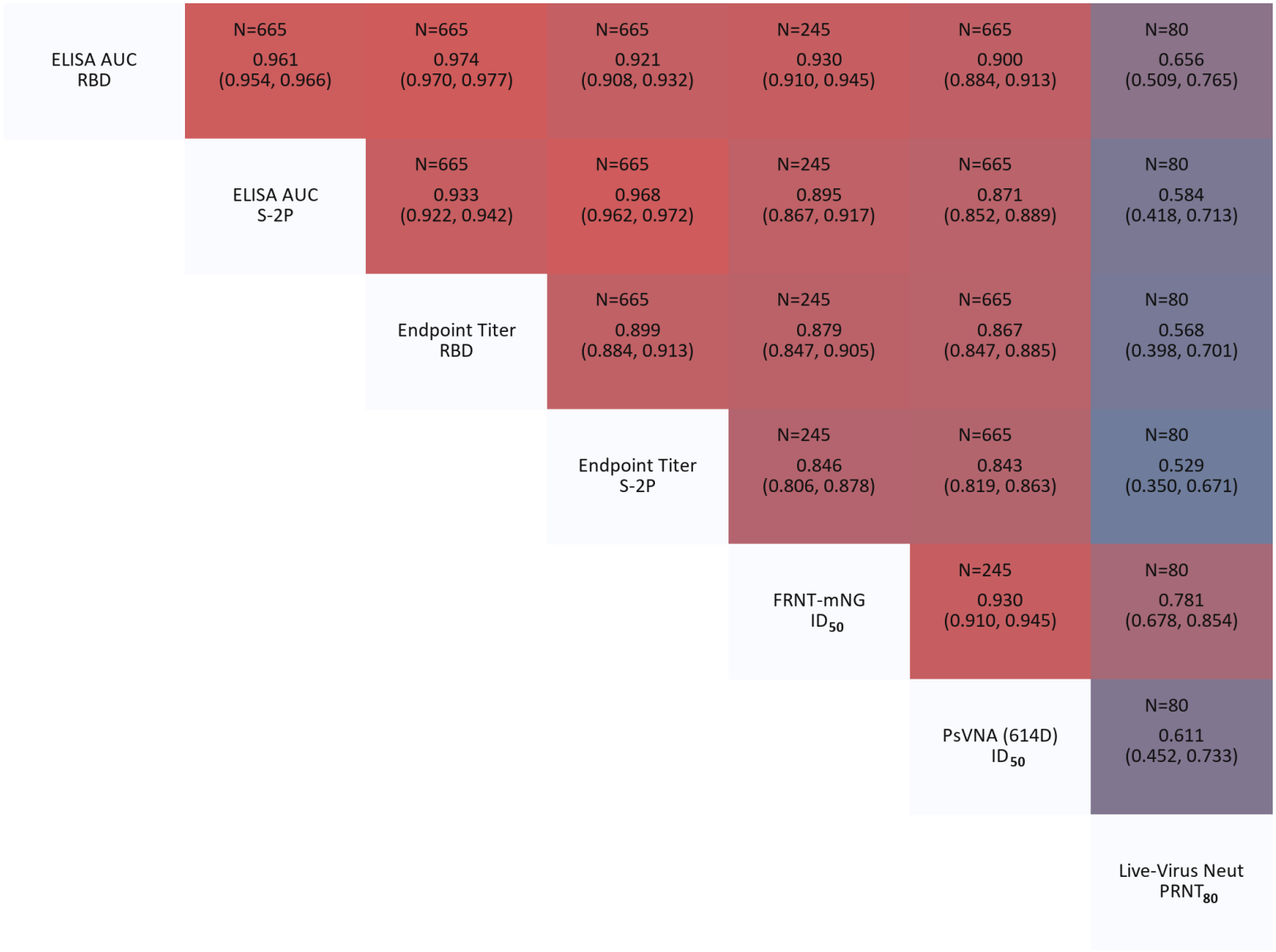


Figure 60: Percentages of CD4 T Cells Expressing Th1 Cytokines S1 Peptide Pool

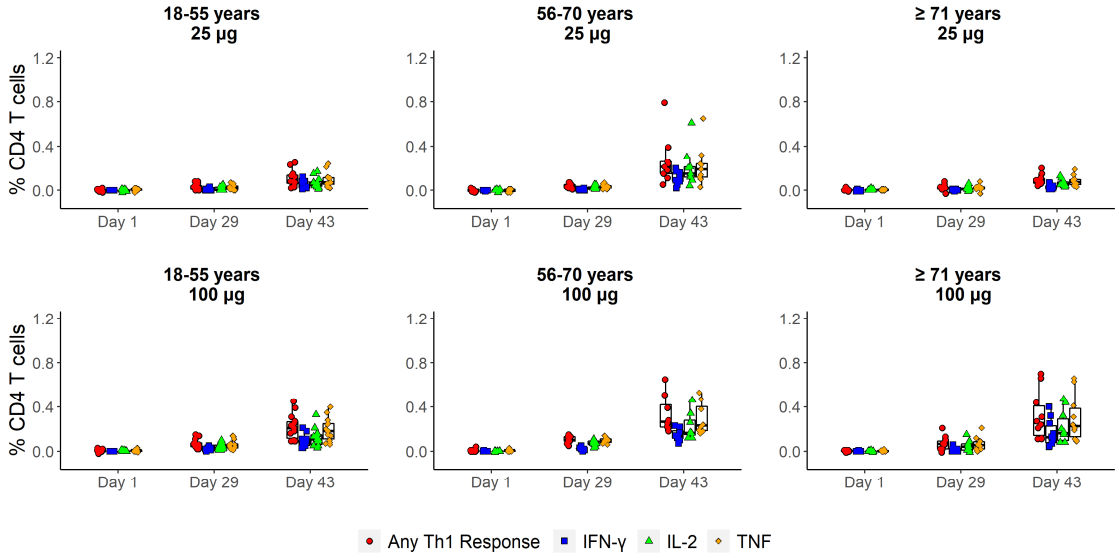


Figure 61: Percentages of CD4 T cells expressing Th2 cytokines S1 Peptide Pool

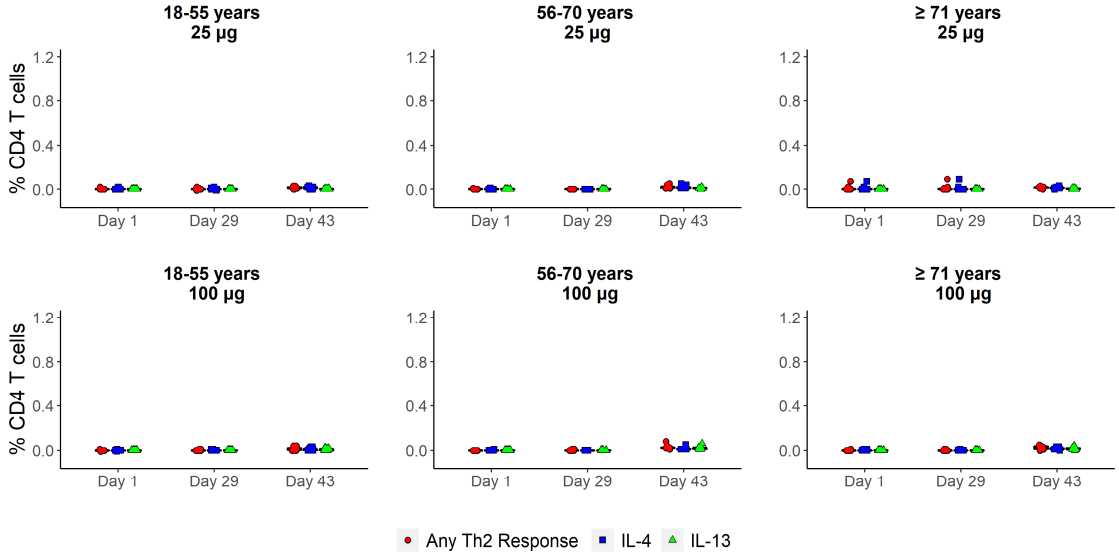


Figure 62: Percentages of CD4 T cells expressing Th1 cytokines S2 Peptide Pool

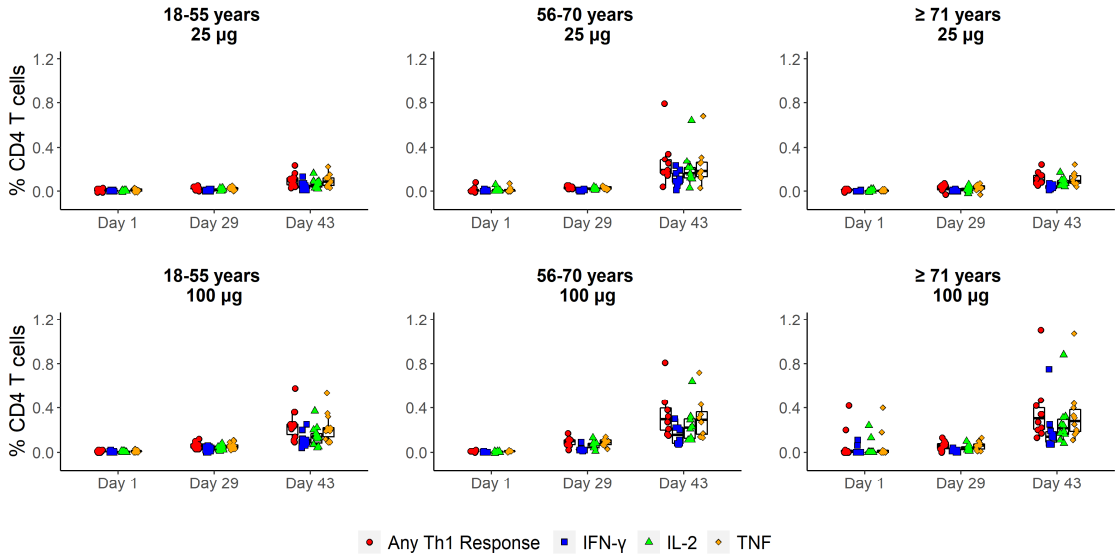


Figure 63: Percentages of CD4 T Cells Expressing Th2 Cytokines S2 Peptide Pool

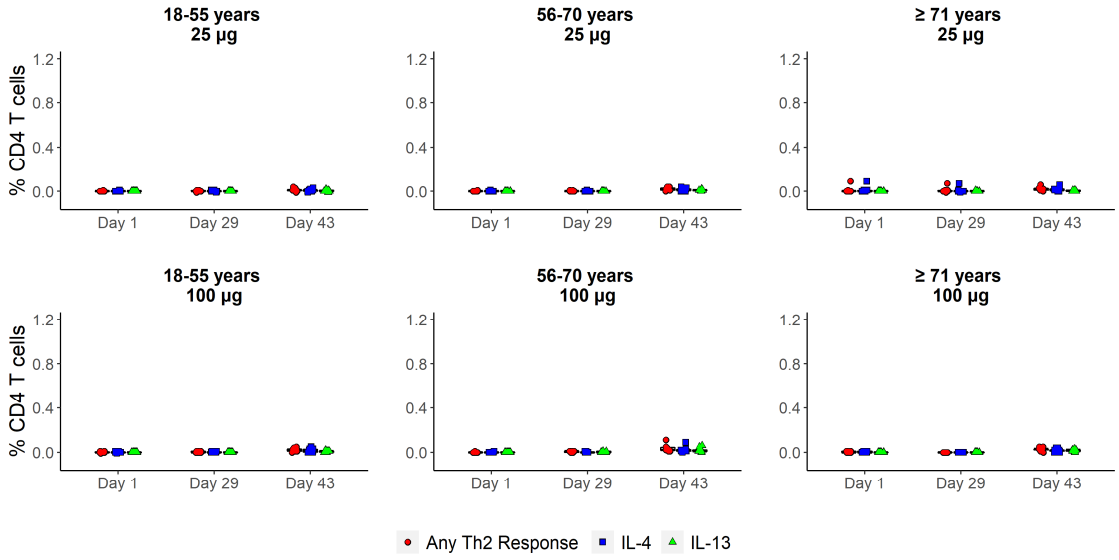


Figure 64: Percentages of CD8 T cells expressing cytokines S1 Peptide Pool

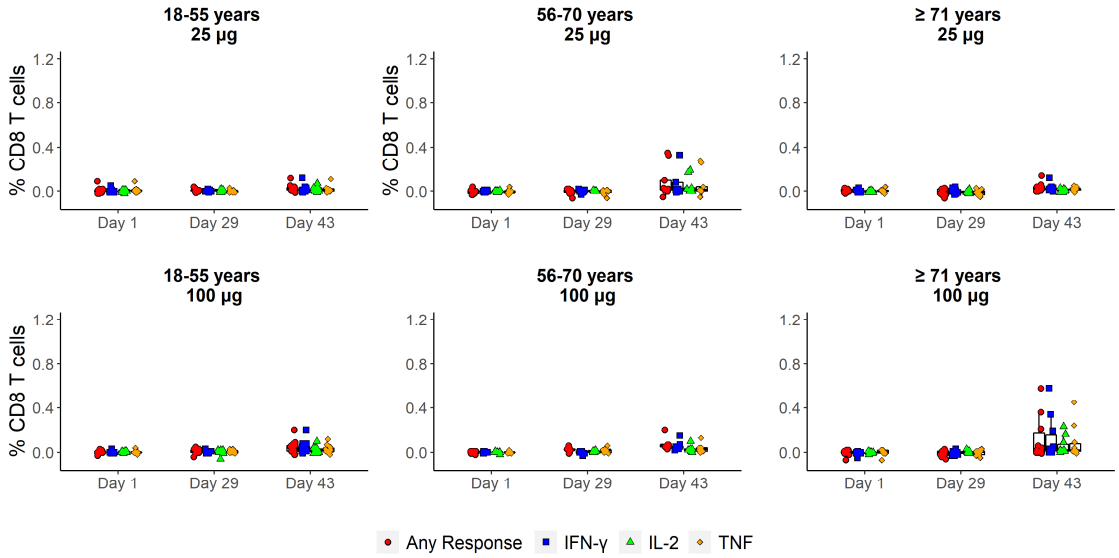


Figure 65: Percentages of CD8 T Cells Expressing Cytokines S2 Peptide Pool

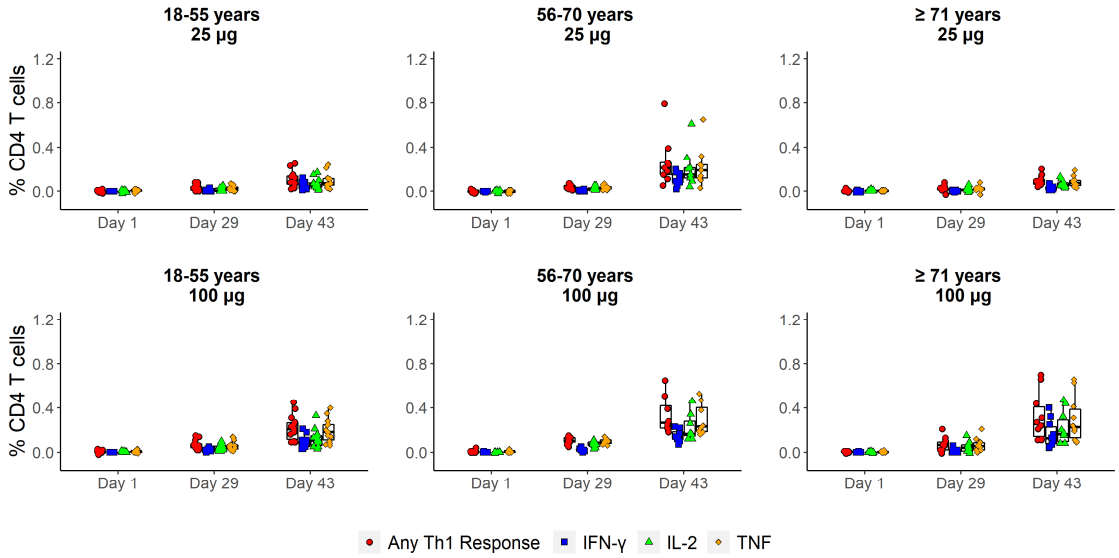


Table 72: Overall Summary of Adverse Events by Treatment Group - All Subjects 18-55 Years of Age

	25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one local solicited adverse event	11	73	14	93	15	100	15	100	55	92
At least one systemic solicited adverse event	8	53	13	87	15	100	15	100	51	85
At least one unsolicited adverse event	12	80	10	67	11	73	11	73	44	73
At least one related unsolicited adverse event	4	27	6	40	3	20	7	47	20	33
Mild (Grade 1)	4	27	5	33	2	13	5	33	16	27
Moderate (Grade 2)	1	7	1	7	2	13	4	27	8	13
Severe (Grade 3)	0	0	0	0	0	0	1	7	1	2
At least one severe (Grade 3) unsolicited adverse event	0	0	0	0	0	0	1	7	1	2
Related	0	0	0	0	0	0	1	7	1	2
Unrelated	0	0	0	0	0	0	0	0	0	0
At least one serious adverse event[b]	0	0	0	0	0	0	0	0	0	0
At least one related, serious adverse event	0	0	0	0	0	0	0	0	0	0
Fatal Event	0	0	0	0	0	0	0	0	0	0
At least one adverse event leading to early termination[c]	0	0	0	0	0	0	0	0	0	0
At least one adverse event leading to discontinuation from Study Vaccination[c]	1	7	0	0	0	0	1	7	2	3
At least one related adverse event leading to early termination[c]	0	0	0	0	0	0	0	0	0	0
At least one related adverse event leading to discontinuation from Study Vaccination[c]	1	7	0	0	0	0	0	0	1	2
At least one medically attended adverse event	4	27	3	20	2	13	4	27	13	22

	25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one new onset chronic medical condition	0	0	0	0	0	0	0	0	0	0
At least one related medically attended adverse event	0	0	0	0	0	0	1	7	1	2
At least one related new onset chronic medical condition	0	0	0	0	0	0	0	0	0	0

N = Number of subjects in the Safety Population
[a]Subjects are counted once for each category regardless of the number of events.
[b]A listing of Serious Adverse Events is included in Table 126.
[c]As reported on the Adverse Event eCRF.

Table 73: Overall Summary of Adverse Events by Treatment Group - All Subjects 56-70 Years of Age

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one local solicited adverse event	8	80	9	90	9	90	26	87
At least one systemic solicited adverse event	8	80	6	60	8	80	22	73
At least one unsolicited adverse event	7	70	7	70	8	80	22	73
At least one related unsolicited adverse event	2	20	1	10	1	10	4	13
Mild (Grade 1)	1	10	0	0	1	10	2	7
Moderate (Grade 2)	1	10	1	10	0	0	2	7
Severe (Grade 3)	0	0	0	0	0	0	0	0
At least one severe (Grade 3) unsolicited adverse event	0	0	1	10	1	10	2	7
Related	0	0	0	0	0	0	0	0
Unrelated	0	0	1	10	1	10	2	7
At least one serious adverse event[b]	0	0	0	0	0	0	0	0
At least one related, serious adverse event	0	0	0	0	0	0	0	0
Fatal Event	0	0	0	0	0	0	0	0
At least one adverse event leading to early termination[c]	0	0	0	0	0	0	0	0
At least one adverse event leading to discontinuation from Study Vaccinationc[c]	0	0	0	0	1	10	1	3
At least one related adverse event leading to early terminationc[c]	0	0	0	0	0	0	0	0
At least one related adverse event leading to discontinuation from Study Vaccinationc[c]	0	0	0	0	0	0	0	0
At least one medically attended adverse event	2	20	3	30	1	10	6	20

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one new onset chronic medical condition	1	10	0	0	0	0	1	3
At least one related medically attended adverse event	0	0	0	0	0	0	0	0
At least one related new onset chronic medical condition	0	0	0	0	0	0	0	0

N = Number of subjects in the Safety Population
[a]Subjects are counted once for each category regardless of the number of events.
[b]A listing of Serious Adverse Events is included in Table 126.
[c]As reported on the Adverse Event eCRF.

Table 74: Overall Summary of Adverse Events by Treatment Group - All Subjects ≥71 years of Age

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one local solicited adverse event	8	80	7	70	10	100	25	83
At least one systemic solicited adverse event	5	50	6	60	7	70	18	60
At least one unsolicited adverse event	9	90	6	60	8	80	23	77
At least one related unsolicited adverse event	4	40	0	0	3	30	7	23
Mild (Grade 1)	4	40	0	0	3	30	7	23
Moderate (Grade 2)	0	0	0	0	0	0	0	0
Severe (Grade 3)	0	0	0	0	0	0	0	0
At least one severe (Grade 3) unsolicited adverse event	0	0	0	0	0	0	0	0
Related	0	0	0	0	0	0	0	0
Unrelated	0	0	0	0	0	0	0	0
At least one serious adverse event[b]	0	0	0	0	0	0	0	0
At least one related, serious adverse event	0	0	0	0	0	0	0	0
Fatal Event	0	0	0	0	0	0	0	0
At least one adverse event leading to early termination[c]	0	0	0	0	0	0	0	0
At least one adverse event leading to discontinuation from Study Vaccinationc[c]	0	0	0	0	0	0	0	0
At least one related adverse event leading to early terminationc[c]	0	0	0	0	0	0	0	0
At least one related adverse event leading to discontinuation from Study Vaccinationc[c]	0	0	0	0	0	0	0	0
At least one medically attended adverse event	1	10	1	10	3	30	5	17

	25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Subjects[a] with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one new onset chronic medical condition	0	0	0	0	0	0	0	0
At least one related medically attended adverse event	0	0	0	0	0	0	0	0
At least one related new onset chronic medical condition	0	0	0	0	0	0	0	0

N = Number of subjects in the Safety Population
[a]Subjects are counted once for each category regardless of the number of events.
[b]A listing of Serious Adverse Events is included in Table 126.
[c]As reported on the Adverse Event eCRF.

TABLE 75:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Any Symptom - 18-55 Years of Age

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Symptom	**Dose 1**	**None**	5	33	-	-	1	7	-	-	6	10
		Mild	8	53	9	60	10	67	9	60	36	60
		Moderate	2	13	6	40	3	20	5	33	16	27
		Severe	-	-	-	-	1	7	1	7	2	3
		Any Severity	10	67	15	100	14	93	15	100	54	90
	Dose 2	**None**	3	23	-	-	-	-	-	-	3	5
		Mild	7	54	7	47	3	20	1	7	18	32
		Moderate	3	23	7	47	11	73	9	64	30	53
		Severe	-	-	1	7	1	7	4	29	6	11
		Any Severity	10	77	15	100	15	100	14	100	54	95
	Any Dose	**None**	4	27	-	-	-	-	-	-	4	7
		Mild	6	40	6	40	3	20	1	7	16	27
		Moderate	5	33	8	53	11	73	10	67	34	57
		Severe	-	-	1	7	1	7	4	27	6	10
		Any Severity	11	73	15	100	15	100	15	100	56	93

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 76:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Systemic Symptoms - 18-55 Years of Age

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Systemic Symptom	**Dose 1**	**None**	10	67	6	40	5	33	7	47	28	47
		Mild	3	20	6	40	8	53	4	27	21	35
		Moderate	2	13	3	20	2	13	4	27	11	18
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	5	33	9	60	10	67	8	53	32	53
	Dose 2	**None**	6	46	2	13	-	-	-	-	8	14
		Mild	4	31	6	40	3	20	2	14	15	26
		Moderate	3	23	6	40	12	80	9	64	30	53
		Severe	-	-	1	7	-	-	3	21	4	7
		Any Severity	7	54	13	87	15	100	14	100	49	86
	Any Dose	**None**	7	47	2	13	-	-	-	-	9	15
		Mild	3	20	6	40	3	20	3	20	15	25
		Moderate	5	33	6	40	12	80	9	60	32	53
		Severe	-	-	1	7	-	-	3	20	4	7
		Any Severity	8	53	13	87	15	100	15	100	51	85
Arthralgia	**Dose 1**	**None**	15	100	13	87	13	87	14	93	55	92
		Mild	-	-	2	13	1	7	1	7	4	7
		Moderate	-	-	-	-	1	7	-	-	1	2
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	2	13	2	13	1	7	5	8
	Dose 2	**None**	11	85	13	87	13	87	6	43	43	75
		Mild	-	-	1	7	1	7	5	36	7	12
		Moderate	2	15	1	7	1	7	3	21	7	12

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	2	15	2	13	2	13	8	57	14	25
	Any Dose	**None**	13	87	12	80	13	87	7	47	45	75
		Mild	-	-	2	13	-	-	5	33	7	12
		Moderate	2	13	1	7	2	13	3	20	8	13
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	2	13	3	20	2	13	8	53	15	25
Fatigue	**Dose 1**	**None**	11	73	7	47	11	73	10	67	39	65
		Mild	2	13	5	33	3	20	3	20	13	22
		Moderate	2	13	3	20	1	7	2	13	8	13
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	4	27	8	53	4	27	5	33	21	35
	Dose 2	**None**	8	62	5	33	3	20	4	29	20	35
		Mild	4	31	4	27	6	40	2	14	16	28
		Moderate	1	8	6	40	6	40	6	43	19	33
		Severe	-	-	-	-	-	-	2	14	2	4
		Any Severity	5	38	10	67	12	80	10	71	37	65
	Any Dose	**None**	8	53	5	33	3	20	5	33	21	35
		Mild	4	27	4	27	5	33	2	13	15	25
		Moderate	3	20	6	40	7	47	6	40	22	37
		Severe	-	-	-	-	-	-	2	13	2	3
		Any Severity	7	47	10	67	12	80	10	67	39	65
Fever[a]	**Dose 1**	**None**	15	100	15	100	15	100	15	100	60	100
		Mild	-	-	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	-	-	-	-	-	-	-	-	-	-
	Dose 2	**None**	13	100	14	93	9	60	6	43	42	74
		Mild	-	-	1	7	5	33	5	36	11	19
		Moderate	-	-	-	-	1	7	2	14	3	5
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	-	-	1	7	6	40	8	57	15	26
	Any Dose	**None**	15	100	14	93	9	60	7	47	45	75
		Mild	-	-	1	7	5	33	5	33	11	18
		Moderate	-	-	-	-	1	7	2	13	3	5
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	-	-	1	7	6	40	8	53	15	25
Feverishness	**Dose 1**	**None**	15	100	15	100	14	93	13	87	57	95
		Mild	-	-	-	-	1	7	2	13	3	5
		Moderate	-	-	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	7	2	13	3	5
	Dose 2	**None**	12	92	12	80	3	20	2	14	29	51
		Mild	1	8	2	13	8	53	4	29	15	26
		Moderate	-	-	1	7	4	27	5	36	10	18
		Severe	-	-	-	-	-	-	3	21	3	5
		Any Severity	1	8	3	20	12	80	12	86	28	49
	Any Dose	**None**	14	93	12	80	3	20	3	20	32	53
		Mild	1	7	2	13	8	53	4	27	15	25
		Moderate	-	-	1	7	4	27	5	33	10	17
		Severe	-	-	-	-	-	-	3	20	3	5

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	1	7	3	20	12	80	12	80	28	47
Headache	**Dose 1**	**None**	12	80	12	80	11	73	8	53	43	72
		Mild	3	20	3	20	4	27	4	27	14	23
		Moderate	-	-	-	-	-	-	3	20	3	5
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	3	20	3	20	4	27	7	47	17	28
	Dose 2	**None**	10	77	5	33	6	40	-	-	21	37
		Mild	2	15	6	40	5	33	9	64	22	39
		Moderate	1	8	3	20	4	27	4	29	12	21
		Severe	-	-	1	7	-	-	1	7	2	4
		Any Severity	3	23	10	67	9	60	14	100	36	63
	Any Dose	**None**	11	73	5	33	5	33	-	-	21	35
		Mild	3	20	6	40	6	40	9	60	24	40
		Moderate	1	7	3	20	4	27	5	33	13	22
		Severe	-	-	1	7	-	-	1	7	2	3
		Any Severity	4	27	10	67	10	67	15	100	39	65
Myalgia	**Dose 1**	**None**	14	93	13	87	14	93	11	73	52	87
		Mild	1	7	2	13	1	7	4	27	8	13
		Moderate	-	-	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	1	7	2	13	1	7	4	27	8	13
	Dose 2	**None**	10	77	9	60	7	47	1	7	27	47
		Mild	2	15	2	13	2	13	5	36	11	19
		Moderate	1	8	4	27	6	40	7	50	18	32
		Severe	-	-	-	-	-	-	1	7	1	2

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	3	23	6	40	8	53	13	93	30	53
	Any Dose	**None**	11	73	9	60	7	47	2	13	29	48
		Mild	3	20	2	13	2	13	5	33	12	20
		Moderate	1	7	4	27	6	40	7	47	18	30
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	4	27	6	40	8	53	13	87	31	52
Nausea	**Dose 1**	**None**	14	93	14	93	15	100	14	93	57	95
		Mild	-	-	-	-	-	-	1	7	1	2
		Moderate	1	7	1	7	-	-	-	-	2	3
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	1	7	1	7	-	-	1	7	3	5
	Dose 2	**None**	12	92	13	87	8	53	10	71	43	75
		Mild	1	8	2	13	6	40	1	7	10	18
		Moderate	-	-	-	-	1	7	2	14	3	5
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	1	8	2	13	7	47	4	29	14	25
	Any Dose	**None**	13	87	13	87	8	53	11	73	45	75
		Mild	1	7	1	7	6	40	1	7	9	15
		Moderate	1	7	1	7	1	7	2	13	5	8
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	2	13	2	13	7	47	4	27	15	25

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.
[a]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 77:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Local Symptoms - 18-55 Years of Age

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Local Symptom	**Dose 1**	**None**	5	33	2	13	1	7	-	-	8	13
		Mild	10	67	10	67	11	73	9	60	40	67
		Moderate	-	-	3	20	2	13	5	33	10	17
		Severe	-	-	-	-	1	7	1	7	2	3
		Any Severity	10	67	13	87	14	93	15	100	52	87
	Dose 2	**None**	3	23	1	7	-	-	-	-	4	7
		Mild	9	69	11	73	10	67	7	50	37	65
		Moderate	1	8	3	20	4	27	6	43	14	25
		Severe	-	-	-	-	1	7	1	7	2	4
		Any Severity	10	77	14	93	15	100	14	100	53	93
	Any Dose	**None**	4	27	1	7	-	-	-	-	5	8
		Mild	10	67	10	67	9	60	6	40	35	58
		Moderate	1	7	4	27	5	33	8	53	18	30
		Severe	-	-	-	-	1	7	1	7	2	3
		Any Severity	11	73	14	93	15	100	15	100	55	92
Erythema/Redness	**Dose 1**	**None**	15	100	14	93	13	87	13	87	55	92
		Mild	-	-	1	7	2	13	2	13	5	8
		Moderate	-	-	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	1	7	2	13	2	13	5	8
	Dose 2	**None**	12	92	11	73	13	87	11	79	47	82
		Mild	1	8	4	27	2	13	3	21	10	18
		Moderate	-	-	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	1	8	4	27	2	13	3	21	10	18
	Any Dose	**None**	14	93	11	73	13	87	11	73	49	82
		Mild	1	7	4	27	2	13	4	27	11	18
		Moderate	-	-	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	1	7	4	27	2	13	4	27	11	18
Erythema/Redness Measurement (mm)	**Dose 1**	**None**	15	100	15	100	13	87	14	93	57	95
		Mild	-	-	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	1	7	-	-	1	2
		Severe	-	-	-	-	1	7	1	7	2	3
		Any Severity	-	-	-	-	2	13	1	7	3	5
	Dose 2	**None**	13	100	15	100	13	87	11	79	52	91
		Mild	-	-	-	-	1	7	-	-	1	2
		Moderate	-	-	-	-	-	-	2	14	2	4
		Severe	-	-	-	-	1	7	1	7	2	4
		Any Severity	-	-	-	-	2	13	3	21	5	9
	Any Dose	**None**	15	100	15	100	13	87	12	80	55	92
		Mild	-	-	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	1	7	2	13	3	5
		Severe	-	-	-	-	1	7	1	7	2	3
		Any Severity	-	-	-	-	2	13	3	20	5	8
Induration/Swelling	**Dose 1**	**None**	15	100	12	80	12	80	11	73	50	83
		Mild	-	-	3	20	3	20	3	20	9	15
		Moderate	-	-	-	-	-	-	1	7	1	2
		Severe	-	-	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	-	-	3	20	3	20	4	27	10	17
	Dose 2	**None**	13	100	15	100	14	93	11	79	53	93
		Mild	-	-	-	-	1	7	2	14	3	5
		Moderate	-	-	-	-	-	-	1	7	1	2
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	7	3	21	4	7
	Any Dose	**None**	15	100	12	80	12	80	11	73	50	83
		Mild	-	-	3	20	3	20	3	20	9	15
		Moderate	-	-	-	-	-	-	1	7	1	2
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	3	20	3	20	4	27	10	17
Induration/Swelling (mm)	**Dose 1**	**None**	15	100	14	93	13	87	12	80	54	90
		Mild	-	-	-	-	2	13	1	7	3	5
		Moderate	-	-	1	7	-	-	1	7	2	3
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	-	-	1	7	2	13	3	20	6	10
	Dose 2	**None**	13	100	15	100	14	93	11	79	53	93
		Mild	-	-	-	-	-	-	1	7	1	2
		Moderate	-	-	-	-	1	7	2	14	3	5
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	7	3	21	4	7
	Any Dose	**None**	15	100	14	93	13	87	11	73	53	88
		Mild	-	-	-	-	1	7	2	13	3	5
		Moderate	-	-	1	7	1	7	1	7	3	5
		Severe	-	-	-	-	-	-	1	7	1	2
		Any Severity	-	-	1	7	2	13	4	27	7	12

			25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pain	**Dose 1**	**None**	5	33	2	13	1	7	-	-	8	13
		Mild	10	67	11	73	12	80	9	60	42	70
		Moderate	-	-	2	13	2	13	6	40	10	17
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	10	67	13	87	14	93	15	100	52	87
	Dose 2	**None**	3	23	2	13	-	-	-	-	5	9
		Mild	9	69	10	67	11	73	10	71	40	70
		Moderate	1	8	3	20	4	27	4	29	12	21
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	10	77	13	87	15	100	14	100	52	91
	Any Dose	**None**	4	27	1	7	-	-	-	-	5	8
		Mild	10	67	10	67	10	67	8	53	38	63
		Moderate	1	7	4	27	5	33	7	47	17	28
		Severe	-	-	-	-	-	-	-	-	-	-
		Any Severity	11	73	14	93	15	100	15	100	55	92

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 78:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Any Symptom - 56-70 Years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Symptom	**Dose 1**	**None**	3	30	4	40	1	10	8	27
		Mild	5	50	4	40	9	90	18	60
		Moderate	2	20	2	20	-	-	4	13
		Severe	-	-	-	-	-	-	-	-
		Any Severity	7	70	6	60	9	90	22	73
	Dose 2	**None**	-	-	2	20	1	11	3	10
		Mild	6	60	7	70	3	33	16	55
		Moderate	3	30	-	-	5	56	8	28
		Severe	1	10	1	10	-	-	2	7
		Any Severity	10	100	8	80	8	89	26	90
	Any Dose	**None**	-	-	1	10	1	10	2	7
		Mild	4	40	6	60	4	40	14	47
		Moderate	5	50	2	20	5	50	12	40
		Severe	1	10	1	10	-	-	2	7
		Any Severity	10	100	9	90	9	90	28	93

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 79:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Systemic Symptoms - 56-70 Years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Systemic Symptom	**Dose 1**	**None**	5	50	7	70	7	70	19	63
		Mild	3	30	2	20	3	30	8	27
		Moderate	2	20	1	10	-	-	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	5	50	3	30	3	30	11	37
	Dose 2	**None**	3	30	5	50	1	11	9	31
		Mild	5	50	4	40	3	33	12	41
		Moderate	1	10	1	10	5	56	7	24
		Severe	1	10	-	-	-	-	1	3
		Any Severity	7	70	5	50	8	89	20	69
	Any Dose	**None**	2	20	4	40	2	20	8	27
		Mild	4	40	4	40	3	30	11	37
		Moderate	3	30	2	20	5	50	10	33
		Severe	1	10	-	-	-	-	1	3
		Any Severity	8	80	6	60	8	80	22	73
Arthralgia	**Dose 1**	**None**	7	70	10	100	10	100	27	90
		Mild	1	10	-	-	-	-	1	3
		Moderate	2	20	-	-	-	-	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	-	-	-	-	3	10
	Dose 2	**None**	9	90	9	90	7	78	25	86
		Mild	-	-	1	10	1	11	2	7
		Moderate	1	10	-	-	1	11	2	7

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	1	10	2	22	4	14
	Any Dose	**None**	6	60	9	90	8	80	23	77
		Mild	1	10	1	10	1	10	3	10
		Moderate	3	30	-	-	1	10	4	13
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	1	10	2	20	7	23
Fatigue	**Dose 1**	**None**	8	80	9	90	7	70	24	80
		Mild	2	20	1	10	3	30	6	20
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	1	10	3	30	6	20
	Dose 2	**None**	6	60	5	50	2	22	13	45
		Mild	2	20	4	40	2	22	8	28
		Moderate	2	20	1	10	5	56	8	28
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	5	50	7	78	16	55
	Any Dose	**None**	6	60	5	50	3	30	14	47
		Mild	2	20	4	40	2	20	8	27
		Moderate	2	20	1	10	5	50	8	27
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	5	50	7	70	16	53
Fever[a]	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	9	90	9	90	8	89	26	90
		Mild	-	-	1	10	1	11	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	1	10	-	-	-	-	1	3
		Any Severity	1	10	1	10	1	11	3	10
	Any Dose	**None**	9	90	9	90	9	90	27	90
		Mild	-	-	1	10	1	10	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	1	10	-	-	-	-	1	3
		Any Severity	1	10	1	10	1	10	3	10
Feverishness	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	8	80	8	80	4	44	20	69
		Mild	1	10	1	10	3	33	5	17
		Moderate	1	10	1	10	2	22	4	14
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	2	20	5	56	9	31
	Any Dose	**None**	8	80	8	80	5	50	21	70
		Mild	1	10	1	10	3	30	5	17
		Moderate	1	10	1	10	2	20	4	13
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	2	20	5	50	9	30

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	**Dose 1**	**None**	8	80	9	90	10	100	27	90
		Mild	2	20	1	10	-	-	3	10
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	1	10	-	-	3	10
	Dose 2	**None**	7	70	7	70	2	22	16	55
		Mild	2	20	3	30	6	67	11	38
		Moderate	1	10	-	-	1	11	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	3	30	7	78	13	45
	Any Dose	**None**	6	60	7	70	3	30	16	53
		Mild	3	30	3	30	6	60	12	40
		Moderate	1	10	-	-	1	10	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	3	30	7	70	14	47
Myalgia	**Dose 1**	**None**	8	80	9	90	9	90	26	87
		Mild	2	20	1	10	1	10	4	13
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	1	10	1	10	4	13
	Dose 2	**None**	4	40	8	80	2	22	14	48
		Mild	5	50	2	20	3	33	10	34
		Moderate	1	10	-	-	4	44	5	17
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	2	20	7	78	15	52
	Any Dose	**None**	4	40	7	70	3	30	14	47

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Mild	5	50	3	30	3	30	11	37
		Moderate	1	10	-	-	4	40	5	17
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	3	30	7	70	16	53
Nausea	**Dose 1**	**None**	10	100	8	80	10	100	28	93
		Mild	-	-	1	10	-	-	1	3
		Moderate	-	-	1	10	-	-	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	2	20	-	-	2	7
	Dose 2	**None**	8	80	10	100	5	56	23	79
		Mild	2	20	-	-	2	22	4	14
		Moderate	-	-	-	-	2	22	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	4	44	6	21
	Any Dose	**None**	8	80	8	80	6	60	22	73
		Mild	2	20	1	10	2	20	5	17
		Moderate	-	-	1	10	2	20	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	2	20	4	40	8	27

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.
[a]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 80:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Local Symptoms - 56-70 Years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Local Symptom	**Dose 1**	**None**	5	50	4	40	2	20	11	37
		Mild	5	50	4	40	8	80	17	57
		Moderate	-	-	2	20	-	-	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	5	50	6	60	8	80	19	63
	Dose 2	**None**	4	40	2	20	1	11	7	24
		Mild	4	40	7	70	6	67	17	59
		Moderate	2	20	-	-	2	22	4	14
		Severe	-	-	1	10	-	-	1	3
		Any Severity	6	60	8	80	8	89	22	76
	Any Dose	**None**	2	20	1	10	1	10	4	13
		Mild	6	60	6	60	7	70	19	63
		Moderate	2	20	2	20	2	20	6	20
		Severe	-	-	1	10	-	-	1	3
		Any Severity	8	80	9	90	9	90	26	87
Erythema/Redness	**Dose 1**	**None**	9	90	10	100	9	90	28	93
		Mild	1	10	-	-	1	10	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	-	-	1	10	2	7
	Dose 2	**None**	9	90	9	90	7	78	25	86
		Mild	1	10	-	-	2	22	3	10
		Moderate	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	1	10	-	-	1	3
		Any Severity	1	10	1	10	2	22	4	14
	Any Dose	**None**	9	90	9	90	7	70	25	83
		Mild	1	10	-	-	3	30	4	13
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	1	10	-	-	1	3
		Any Severity	1	10	1	10	3	30	5	17
Erythema/Redness Measurement (mm)	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	9	90	9	90	8	89	26	90
		Mild	-	-	-	-	1	11	1	3
		Moderate	1	10	-	-	-	-	1	3
		Severe	-	-	1	10	-	-	1	3
		Any Severity	1	10	1	10	1	11	3	10
	Any Dose	**None**	9	90	9	90	9	90	27	90
		Mild	-	-	-	-	1	10	1	3
		Moderate	1	10	-	-	-	-	1	3
		Severe	-	-	1	10	-	-	1	3
		Any Severity	1	10	1	10	1	10	3	10
Induration/Swelling	**Dose 1**	**None**	8	80	8	80	7	70	23	77
		Mild	2	20	-	-	3	30	5	17
		Moderate	-	-	2	20	-	-	2	7
		Severe	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	2	20	2	20	3	30	7	23
	Dose 2	**None**	6	60	9	90	7	78	22	76
		Mild	4	40	-	-	1	11	5	17
		Moderate	-	-	1	10	1	11	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	1	10	2	22	7	24
	Any Dose	**None**	5	50	7	70	7	70	19	63
		Mild	5	50	-	-	2	20	7	23
		Moderate	-	-	3	30	1	10	4	13
		Severe	-	-	-	-	-	-	-	-
		Any Severity	5	50	3	30	3	30	11	37
Induration/Swelling (mm)	**Dose 1**	**None**	9	90	8	80	10	100	27	90
		Mild	1	10	-	-	-	-	1	3
		Moderate	-	-	2	20	-	-	2	7
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	2	20	-	-	3	10
	Dose 2	**None**	8	80	9	90	8	89	25	86
		Mild	-	-	-	-	-	-	-	-
		Moderate	2	20	1	10	1	11	4	14
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	1	10	1	11	4	14
	Any Dose	**None**	7	70	7	70	9	90	23	77
		Mild	1	10	-	-	-	-	1	3
		Moderate	2	20	3	30	1	10	6	20
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	3	30	1	10	7	23

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pain	**Dose 1**	**None**	7	70	4	40	2	20	13	43
		Mild	3	30	6	60	8	80	17	57
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	6	60	8	80	17	57
	Dose 2	**None**	5	50	2	20	1	11	8	28
		Mild	5	50	7	70	6	67	18	62
		Moderate	-	-	1	10	2	22	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	5	50	8	80	8	89	21	72
	Any Dose	**None**	4	40	1	10	1	10	6	20
		Mild	6	60	8	80	7	70	21	70
		Moderate	-	-	1	10	2	20	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	9	90	9	90	24	80

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 81:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Any Symptom - ≥71 years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Symptom	**Dose 1**	**None**	1	10	2	20	2	20	5	17
		Mild	9	90	7	70	8	80	24	80
		Moderate	-	-	1	10	-	-	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	9	90	8	80	8	80	25	83
	Dose 2	**None**	1	10	3	30	-	-	4	13
		Mild	7	70	6	60	5	50	18	60
		Moderate	2	20	1	10	4	40	7	23
		Severe	-	-	-	-	1	10	1	3
		Any Severity	9	90	7	70	10	100	26	87
	Any Dose	**None**	-	-	2	20	-	-	2	7
		Mild	8	80	6	60	5	50	19	63
		Moderate	2	20	2	20	4	40	8	27
		Severe	-	-	-	-	1	10	1	3
		Any Severity	10	100	8	80	10	100	28	93

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 82:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Systemic Symptoms - ≥71 years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Systemic Symptom	**Dose 1**	**None**	5	50	6	60	7	70	18	60
		Mild	5	50	3	30	3	30	11	37
		Moderate	-	-	1	10	-	-	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	5	50	4	40	3	30	12	40
	Dose 2	**None**	7	70	4	40	3	30	14	47
		Mild	3	30	5	50	3	30	11	37
		Moderate	-	-	1	10	3	30	4	13
		Severe	-	-	-	-	1	10	1	3
		Any Severity	3	30	6	60	7	70	16	53
	Any Dose	**None**	5	50	4	40	3	30	12	40
		Mild	5	50	4	40	3	30	12	40
		Moderate	-	-	2	20	3	30	5	17
		Severe	-	-	-	-	1	10	1	3
		Any Severity	5	50	6	60	7	70	18	60
Arthralgia	**Dose 1**	**None**	9	90	9	90	10	100	28	93
		Mild	1	10	1	10	-	-	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	1	10	-	-	2	7
	Dose 2	**None**	10	100	10	100	8	80	28	93
		Mild	-	-	-	-	2	20	2	7
		Moderate	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	2	20	2	7
	Any Dose	**None**	9	90	9	90	8	80	26	87
		Mild	1	10	1	10	2	20	4	13
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	1	10	2	20	4	13
Fatigue	**Dose 1**	**None**	8	80	6	60	7	70	21	70
		Mild	2	20	3	30	3	30	8	27
		Moderate	-	-	1	10	-	-	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	4	40	3	30	9	30
	Dose 2	**None**	9	90	5	50	3	30	17	57
		Mild	1	10	4	40	3	30	8	27
		Moderate	-	-	1	10	3	30	4	13
		Severe	-	-	-	-	1	10	1	3
		Any Severity	1	10	5	50	7	70	13	43
	Any Dose	**None**	7	70	5	50	3	30	15	50
		Mild	3	30	3	30	3	30	9	30
		Moderate	-	-	2	20	3	30	5	17
		Severe	-	-	-	-	1	10	1	3
		Any Severity	3	30	5	50	7	70	15	50
Fever[a]	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	10	100	10	100	9	90	29	97
		Mild	-	-	-	-	1	10	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	10	1	3
	Any Dose	**None**	10	100	10	100	9	90	29	97
		Mild	-	-	-	-	1	10	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	10	1	3
Feverishness	**Dose 1**	**None**	10	100	10	100	9	90	29	97
		Mild	-	-	-	-	1	10	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	10	1	3
	Dose 2	**None**	10	100	10	100	6	60	26	87
		Mild	-	-	-	-	3	30	3	10
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	4	40	4	13
	Any Dose	**None**	10	100	10	100	5	50	25	83
		Mild	-	-	-	-	4	40	4	13
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	5	50	5	17

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	**Dose 1**	**None**	7	70	9	90	10	100	26	87
		Mild	3	30	1	10	-	-	4	13
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	1	10	-	-	4	13
	Dose 2	**None**	8	80	10	100	6	60	24	80
		Mild	2	20	-	-	3	30	5	17
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	4	40	6	20
	Any Dose	**None**	6	60	9	90	6	60	21	70
		Mild	4	40	1	10	3	30	8	27
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	4	40	1	10	4	40	9	30
Myalgia	**Dose 1**	**None**	7	70	10	100	8	80	25	83
		Mild	3	30	-	-	2	20	5	17
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	-	-	2	20	5	17
	Dose 2	**None**	9	90	8	80	4	40	21	70
		Mild	1	10	2	20	5	50	8	27
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	2	20	6	60	9	30
	Any Dose	**None**	7	70	8	80	4	40	19	63

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Mild	3	30	2	20	5	50	10	33
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	2	20	6	60	11	37
Nausea	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	10	100	10	100	9	90	29	97
		Mild	-	-	-	-	1	10	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	10	1	3
	Any Dose	**None**	10	100	10	100	9	90	29	97
		Mild	-	-	-	-	1	10	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	1	10	1	3

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.
[a]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 83:
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Treatment Group – Local Symptoms - ≥71 years of Age

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Local Symptom	**Dose 1**	**None**	4	40	3	30	2	20	9	30
		Mild	6	60	7	70	8	80	21	70
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	7	70	8	80	21	70
	Dose 2	**None**	3	30	6	60	-	-	9	30
		Mild	5	50	4	40	6	60	15	50
		Moderate	2	20	-	-	4	40	6	20
		Severe	-	-	-	-	-	-	-	-
		Any Severity	7	70	4	40	10	100	21	70
	Any Dose	**None**	2	20	3	30	-	-	5	17
		Mild	6	60	7	70	6	60	19	63
		Moderate	2	20	-	-	4	40	6	20
		Severe	-	-	-	-	-	-	-	-
		Any Severity	8	80	7	70	10	100	25	83
Erythema/Redness	**Dose 1**	**None**	9	90	9	90	10	100	28	93
		Mild	1	10	1	10	-	-	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	1	10	1	10	-	-	2	7
	Dose 2	**None**	7	70	10	100	6	60	23	77
		Mild	3	30	-	-	4	40	7	23
		Moderate	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	-	-	4	40	7	23
	Any Dose	**None**	7	70	9	90	6	60	22	73
		Mild	3	30	1	10	4	40	8	27
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	3	30	1	10	4	40	8	27
Erythema/Redness Measurement (mm)	**Dose 1**	**None**	10	100	10	100	10	100	30	100
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	-	-	-	-	-	-
	Dose 2	**None**	8	80	10	100	8	80	26	87
		Mild	-	-	-	-	1	10	1	3
		Moderate	2	20	-	-	1	10	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	2	20	4	13
	Any Dose	**None**	8	80	10	100	8	80	26	87
		Mild	-	-	-	-	1	10	1	3
		Moderate	2	20	-	-	1	10	3	10
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	2	20	4	13
Induration/Swelling	**Dose 1**	**None**	10	100	8	80	10	100	28	93
		Mild	-	-	2	20	-	-	2	7
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Any Severity	-	-	2	20	-	-	2	7
	Dose 2	**None**	8	80	10	100	7	70	25	83
		Mild	2	20	-	-	3	30	5	17
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	3	30	5	17
	Any Dose	**None**	8	80	8	80	7	70	23	77
		Mild	2	20	2	20	3	30	7	23
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	2	20	3	30	7	23
Induration/Swelling (mm)	**Dose 1**	**None**	10	100	9	90	10	100	29	97
		Mild	-	-	1	10	-	-	1	3
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	-	-	1	10	-	-	1	3
	Dose 2	**None**	8	80	10	100	7	70	25	83
		Mild	-	-	-	-	-	-	-	-
		Moderate	2	20	-	-	3	30	5	17
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	-	-	3	30	5	17
	Any Dose	**None**	8	80	9	90	7	70	24	80
		Mild	-	-	1	10	-	-	1	3
		Moderate	2	20	-	-	3	30	5	17
		Severe	-	-	-	-	-	-	-	-
		Any Severity	2	20	1	10	3	30	6	20

			25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Symptom	**Dose**	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pain	**Dose 1**	**None**	4	40	3	30	2	20	9	30
		Mild	6	60	7	70	8	80	21	70
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	7	70	8	80	21	70
	Dose 2	**None**	4	40	6	60	-	-	10	33
		Mild	6	60	4	40	9	90	19	63
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	6	60	4	40	10	100	20	67
	Any Dose	**None**	2	20	3	30	-	-	5	17
		Mild	8	80	7	70	9	90	24	80
		Moderate	-	-	-	-	1	10	1	3
		Severe	-	-	-	-	-	-	-	-
		Any Severity	8	80	7	70	10	100	25	83

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 84:
Summary of Duration of Solicited Symptoms by Treatment Group - All Subjects 18-55 Years of Age

		25 µg mRNA-1273 (N=15)			50 µg mRNA -1273 (N=15)			100 µg mRNA -1273 (N=15)			250 µg mRNA -1273 (N=15)			All Subjects (N=60)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
Any Symptom	n	21	27	48	35	52	87	34	77	111	47	97	144	137	253	390
	Mean	1.3	1.5	1.4	1.9	1.6	1.7	1.5	1.7	1.7	2.2	1.9	2.0	1.8	1.8	1.8
	Standard Deviation	0.6	0.8	0.7	1.1	0.8	0.9	0.6	1.0	0.9	1.2	1.0	1.1	1.0	0.9	1.0
	Median	1.0	1.0	1.0	2.0	1.0	1.0	1.5	1.0	1.0	2.0	2.0	2.0	2.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	3	3	6	3	6	3	5	5	5	6	6	6	6	6
Any Local Symptom	n	10	12	22	17	17	34	22	19	41	25	22	47	74	70	144
	Mean	1.7	2.0	1.9	2.1	1.8	1.9	1.7	2.7	2.1	2.3	2.6	2.4	2.0	2.3	2.2
	Standard Deviation	0.7	0.9	0.8	0.9	0.8	0.9	0.6	1.2	1.1	1.2	1.0	1.1	0.9	1.1	1.0
	Median	2.0	2.0	2.0	2.0	2.0	2.0	2.0	3.0	2.0	2.0	3.0	3.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	3	3	4	3	4	3	5	5	5	4	5	5	5	5
Erythema/redness	n	-	1	1	1	4	5	3	2	5	3	3	6	7	10	17
	Mean	-	2.0	2.0	1.0	1.0	1.0	1.3	3.0	2.0	1.0	3.3	2.2	1.1	2.2	1.8
	Standard Deviation	-	.	.	.	0.0	0.0	0.6	2.8	1.7	0.0	0.6	1.3	0.4	1.5	1.3
	Median	-	2.0	2.0	1.0	1.0	1.0	1.0	3.0	1.0	1.0	3.0	2.0	1.0	1.5	1.0
	Minimum	-	2	2	1	1	1	1	1	1	1	3	1	1	1	1
	Maximum	-	2	2	1	1	1	2	5	5	1	4	4	2	5	5
Induration/swelling	n	-	-	-	3	-	3	4	1	5	6	3	9	13	4	17
	Mean	-	-	-	2.0	-	2.0	1.8	4.0	2.2	1.7	2.7	2.0	1.8	3.0	2.1
	Standard Deviation	-	-	-	1.7	-	1.7	1.0	.	1.3	1.2	0.6	1.1	1.2	0.8	1.2
	Median	-	-	-	1.0	-	1.0	1.5	4.0	2.0	1.0	3.0	2.0	1.0	3.0	2.0

		25 µg mRNA-1273 (N=15)			50 µg mRNA -1273 (N=15)			100 µg mRNA -1273 (N=15)			250 µg mRNA -1273 (N=15)			All Subjects (N=60)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	-	-	-	1	-	1	1	4	1	1	2	1	1	2	1
	Maximum	-	-	-	4	-	4	3	4	4	4	3	4	4	4	4
Pain	n	10	11	21	13	13	26	15	16	31	16	16	32	54	56	110
	Mean	1.7	2.0	1.9	2.2	2.1	2.1	1.7	2.6	2.2	2.8	2.5	2.6	2.1	2.3	2.2
	Standard Deviation	0.7	0.9	0.8	0.7	0.8	0.7	0.5	1.1	0.9	1.0	1.1	1.0	0.8	1.0	0.9
	Median	2.0	2.0	2.0	2.0	2.0	2.0	2.0	3.0	2.0	3.0	3.0	3.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	3	3	3	3	3	2	5	5	5	4	5	5	5	5
Any Sytemic Symptom	n	11	15	26	18	35	53	12	58	70	22	75	97	63	183	246
	Mean	1.0	1.1	1.1	1.7	1.5	1.6	1.3	1.4	1.4	2.2	1.7	1.8	1.7	1.5	1.6
	Standard Deviation	0.0	0.4	0.3	1.3	0.8	1.0	0.5	0.7	0.6	1.3	0.9	1.0	1.1	0.8	0.9
	Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	2.0	1.0	2.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	1	2	2	6	3	6	2	4	4	5	6	6	6	6	6
Arthralgia	n	-	2	2	2	2	4	2	2	4	2	8	10	6	14	20
	Mean	-	1.0	1.0	1.0	2.0	1.5	1.0	1.0	1.0	3.0	1.4	1.7	1.7	1.4	1.5
	Standard Deviation	-	0.0	0.0	0.0	1.4	1.0	0.0	0.0	0.0	1.4	0.5	0.9	1.2	0.6	0.8
	Median	-	1.0	1.0	1.0	2.0	1.0	1.0	1.0	1.0	3.0	1.0	1.5	1.0	1.0	1.0
	Minimum	-	1	1	1	1	1	1	1	1	2	1	1	1	1	1
	Maximum	-	1	1	1	3	3	1	1	1	4	2	4	4	3	4
Fatigue	n	4	5	9	9	11	20	4	12	16	5	13	18	22	41	63
	Mean	1.0	1.2	1.1	2.1	1.8	2.0	1.5	1.6	1.6	3.2	2.4	2.6	2.0	1.9	1.9
	Standard Deviation	0.0	0.4	0.3	1.6	0.9	1.2	0.6	0.7	0.6	1.8	1.4	1.5	1.5	1.1	1.2
	Median	1.0	1.0	1.0	2.0	2.0	2.0	1.5	1.5	1.5	3.0	2.0	2.0	1.5	2.0	2.0

		25 µg mRNA-1273 (N=15)			50 µg mRNA -1273 (N=15)			100 µg mRNA -1273 (N=15)			250 µg mRNA -1273 (N=15)			All Subjects (N=60)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	1	2	2	6	3	6	2	3	3	5	6	6	6	6	6
Fever	n	-	-	-	-	1	1	-	6	6	-	8	8	-	15	15
	Mean	-	-	-	-	1.0	1.0	-	1.2	1.2	-	1.3	1.3	-	1.2	1.2
	Standard Deviation	-	-	-	-	.	.	-	0.4	0.4	-	0.5	0.5	-	0.4	0.4
	Median	-	-	-	-	1.0	1.0	-	1.0	1.0	-	1.0	1.0	-	1.0	1.0
	Minimum	-	-	-	-	1	1	-	1	1	-	1	1	-	1	1
	Maximum	-	-	-	-	1	1	-	2	2	-	2	2	-	2	2
Feverishness	n	-	1	1	-	3	3	1	12	13	2	12	14	3	28	31
	Mean	-	1.0	1.0	-	1.0	1.0	2.0	1.3	1.3	1.0	1.6	1.5	1.3	1.4	1.4
	Standard Deviation	-	.	.	-	0.0	0.0	.	0.5	0.5	0.0	0.5	0.5	0.6	0.5	0.5
	Median	-	1.0	1.0	-	1.0	1.0	2.0	1.0	1.0	1.0	2.0	1.5	1.0	1.0	1.0
	Minimum	-	1	1	-	1	1	2	1	1	1	1	1	1	1	1
	Maximum	-	1	1	-	1	1	2	2	2	1	2	2	2	2	2
Headache	n	5	3	8	3	10	13	4	9	13	8	17	25	20	39	59
	Mean	1.0	1.0	1.0	1.7	1.3	1.4	1.0	1.4	1.3	1.9	1.6	1.7	1.5	1.4	1.4
	Standard Deviation	0.0	0.0	0.0	1.2	0.5	0.7	0.0	1.0	0.9	1.0	0.8	0.9	0.8	0.8	0.8
	Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.5	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	1	1	1	3	2	3	1	4	4	3	3	3	3	4	4
Myalgia	n	1	3	4	2	6	8	1	10	11	4	13	17	8	32	40
	Mean	1.0	1.3	1.3	1.0	1.8	1.6	1.0	1.7	1.6	1.8	1.8	1.8	1.4	1.8	1.7
	Standard Deviation	.	0.6	0.5	0.0	1.0	0.9	.	0.8	0.8	1.0	0.9	0.9	0.7	0.8	0.8
	Median	1.0	1.0	1.0	1.0	1.5	1.0	1.0	1.5	1.0	1.5	2.0	2.0	1.0	2.0	1.0

		25 µg mRNA-1273 (N=15)			50 µg mRNA -1273 (N=15)			100 µg mRNA -1273 (N=15)			250 µg mRNA -1273 (N=15)			All Subjects (N=60)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	1	2	2	1	3	3	1	3	3	3	4	4	3	4	4
Nausea	n	1	1	2	2	2	4	-	7	7	1	4	5	4	14	18
	Mean	1.0	1.0	1.0	1.0	1.0	1.0	-	1.3	1.3	2.0	1.0	1.2	1.3	1.1	1.2
	Standard Deviation	.	.	0.0	0.0	0.0	0.0	-	0.5	0.5	.	0.0	0.4	0.5	0.4	0.4
	Median	1.0	1.0	1.0	1.0	1.0	1.0	-	1.0	1.0	2.0	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	-	1	1	2	1	1	1	1	1
	Maximum	1	1	1	1	1	1	-	2	2	2	1	2	2	2	2
n=number of solicited adverse events																

TABLE 85:
Summary of Duration of Solicited Symptoms by Treatment Group - All Subjects 56-70 Years of Age

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
Any Symptom	n	19	32	51	13	24	37	18	47	65	50	103	153
	Mean	1.6	1.6	1.6	1.6	2.0	1.9	1.3	1.8	1.7	1.5	1.8	1.7
	Standard Deviation	1.6	0.8	1.2	0.7	1.2	1.1	0.5	1.0	0.9	1.1	1.0	1.0
	Median	1.0	1.0	1.0	2.0	2.0	2.0	1.0	2.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	8	4	8	3	5	5	2	5	5	8	5	8
Any Local Symptom	n	7	12	19	8	10	18	12	13	25	27	35	62
	Mean	2.3	1.8	1.9	1.9	2.6	2.3	1.4	2.4	1.9	1.8	2.2	2.0
	Standard Deviation	2.6	0.8	1.6	0.6	1.3	1.1	0.5	1.3	1.1	1.4	1.1	1.3
	Median	1.0	2.0	2.0	2.0	2.5	2.0	1.0	2.0	2.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	8	3	8	3	5	5	2	5	5	8	5	8
Erythema/redness	n	2	2	4	-	1	1	1	3	4	3	6	9
	Mean	4.5	2.0	3.3	-	3.0	3.0	1.0	2.3	2.0	3.3	2.3	2.7
	Standard Deviation	4.9	0.0	3.2	-	.	.	.	2.3	2.0	4.0	1.5	2.4
	Median	4.5	2.0	2.0	-	3.0	3.0	1.0	1.0	1.0	1.0	2.0	2.0
	Minimum	1	2	1	-	3	3	1	1	1	1	1	1
	Maximum	8	2	8	-	3	3	1	5	5	8	5	8
Induration/swelling	n	2	4	6	2	1	3	3	2	5	7	7	14
	Mean	1.5	1.8	1.7	1.5	5.0	2.7	1.3	3.0	2.0	1.4	2.6	2.0
	Standard Deviation	0.7	1.0	0.8	0.7	.	2.1	0.6	1.4	1.2	0.5	1.5	1.2
	Median	1.5	1.5	1.5	1.5	5.0	2.0	1.0	3.0	2.0	1.0	2.0	2.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	1	1	1	1	5	1	1	2	1	1	1	1
	Maximum	2	3	3	2	5	5	2	4	4	2	5	5
Pain	n	3	6	9	6	8	14	8	8	16	17	22	39
	Mean	1.3	1.7	1.6	2.0	2.3	2.1	1.5	2.3	1.9	1.6	2.1	1.9
	Standard Deviation	0.6	0.8	0.7	0.6	1.0	0.9	0.5	0.9	0.8	0.6	0.9	0.8
	Median	1.0	1.5	1.0	2.0	2.0	2.0	1.5	2.0	2.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	2	3	3	3	4	4	2	4	4	3	4	4
Any Sytemic Symptom	n	12	20	32	5	14	19	6	34	40	23	68	91
	Mean	1.3	1.5	1.4	1.2	1.6	1.5	1.2	1.6	1.5	1.2	1.5	1.5
	Standard Deviation	0.5	0.9	0.8	0.4	1.1	1.0	0.4	0.8	0.8	0.4	0.9	0.8
	Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	2	4	4	2	5	5	2	4	4	2	5	5
Arthralgia	n	5	1	6	-	1	1	-	2	2	5	4	9
	Mean	1.2	1.0	1.2	-	2.0	2.0	-	2.0	2.0	1.2	1.8	1.4
	Standard Deviation	0.4	.	0.4	-	.	.	-	0.0	0.0	0.4	0.5	0.5
	Median	1.0	1.0	1.0	-	2.0	2.0	-	2.0	2.0	1.0	2.0	1.0
	Minimum	1	1	1	-	2	2	-	2	2	1	1	1
	Maximum	2	1	2	-	2	2	-	2	2	2	2	2
Fatigue	n	2	5	7	1	5	6	5	7	12	8	17	25
	Mean	1.5	1.8	1.7	1.0	2.4	2.2	1.2	2.1	1.8	1.3	2.1	1.8
	Standard Deviation	0.7	1.1	1.0	.	1.5	1.5	0.4	1.2	1.1	0.5	1.2	1.1
	Median	1.5	1.0	1.0	1.0	2.0	2.0	1.0	2.0	1.0	1.0	2.0	1.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	2	3	3	1	5	5	2	4	4	2	5	5
Fever	n	-	1	1	-	1	1	-	1	1	-	3	3
	Mean	-	2.0	2.0	-	1.0	1.0	-	1.0	1.0	-	1.3	1.3
	Standard Deviation	-	.	.	-	.	.	-	.	.	-	0.6	0.6
	Median	-	2.0	2.0	-	1.0	1.0	-	1.0	1.0	-	1.0	1.0
	Minimum	-	2	2	-	1	1	-	1	1	-	1	1
	Maximum	-	2	2	-	1	1	-	1	1	-	2	2
Feverishness	n	-	2	2	-	2	2	-	5	5	-	9	9
	Mean	-	1.0	1.0	-	1.0	1.0	-	1.2	1.2	-	1.1	1.1
	Standard Deviation	-	0.0	0.0	-	0.0	0.0	-	0.4	0.4	-	0.3	0.3
	Median	-	1.0	1.0	-	1.0	1.0	-	1.0	1.0	-	1.0	1.0
	Minimum	-	1	1	-	1	1	-	1	1	-	1	1
	Maximum	-	1	1	-	1	1	-	2	2	-	2	2
Headache	n	3	3	6	1	3	4	-	8	8	4	14	18
	Mean	1.0	1.3	1.2	1.0	1.0	1.0	-	1.4	1.4	1.0	1.3	1.2
	Standard Deviation	0.0	0.6	0.4	.	0.0	0.0	-	0.5	0.5	0.0	0.5	0.4
	Median	1.0	1.0	1.0	1.0	1.0	1.0	-	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	-	1	1	1	1	1
	Maximum	1	2	2	1	1	1	-	2	2	1	2	2
Myalgia	n	2	6	8	1	2	3	1	7	8	4	15	19
	Mean	1.5	1.5	1.5	2.0	1.5	1.7	1.0	1.6	1.5	1.5	1.5	1.5
	Standard Deviation	0.7	1.2	1.1	.	0.7	0.6	.	0.8	0.8	0.6	0.9	0.8
	Median	1.5	1.0	1.0	2.0	1.5	2.0	1.0	1.0	1.0	1.5	1.0	1.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**	**Dose 1**	**Dose 2**	**All**
	Minimum	1	1	1	2	1	1	1	1	1	1	1	1
	Maximum	2	4	4	2	2	2	1	3	3	2	4	4
Nausea	n	-	2	2	2	-	2	-	4	4	2	6	8
	Mean	-	1.0	1.0	1.0	-	1.0	-	1.3	1.3	1.0	1.2	1.1
	Standard Deviation	-	0.0	0.0	0.0	-	0.0	-	0.5	0.5	0.0	0.4	0.4
	Median	-	1.0	1.0	1.0	-	1.0	-	1.0	1.0	1.0	1.0	1.0
	Minimum	-	1	1	1	-	1	-	1	1	1	1	1
	Maximum	-	1	1	1	-	1	-	2	2	1	2	2
n=number of solicited adverse events													

TABLE 86:
Summary of Duration of Solicited Symptoms by Treatment Group - All Subjects ≥71 years of Age

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**
Any Symptom	n	18	16	34	19	12	31	14	47	61	51	75	126
	Mean	1.7	1.8	1.7	1.9	2.1	2.0	1.7	1.7	1.7	1.8	1.8	1.8
	Standard Deviation	1.3	1.4	1.3	1.4	1.2	1.3	0.7	1.0	1.0	1.2	1.1	1.2
	Median	1.0	1.0	1.0	1.0	2.0	1.0	2.0	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	6	6	6	5	5	5	3	4	4	6	6	6
Any Local Symptom	n	7	12	19	12	5	17	8	18	26	27	35	62
	Mean	1.7	2.1	1.9	2.2	2.2	2.2	1.9	2.3	2.2	2.0	2.2	2.1
	Standard Deviation	0.8	1.6	1.3	1.6	0.8	1.4	0.6	1.2	1.1	1.2	1.3	1.2
	Median	2.0	1.5	2.0	1.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	6	6	5	3	5	3	4	4	5	6	6
Erythema/redness	n	1	3	4	1	-	1	-	4	4	2	7	9
	Mean	2.0	3.0	2.8	4.0	-	4.0	-	2.3	2.3	3.0	2.6	2.7
	Standard Deviation	.	2.6	2.2	.	-	.	-	1.3	1.3	1.4	1.8	1.7
	Median	2.0	2.0	2.0	4.0	-	4.0	-	2.0	2.0	3.0	2.0	2.0
	Minimum	2	1	1	4	-	4	-	1	1	2	1	1
	Maximum	2	6	6	4	-	4	-	4	4	4	6	6
Induration/swelling	n	-	2	2	4	-	4	-	3	3	4	5	9
	Mean	-	2.0	2.0	2.5	-	2.5	-	2.0	2.0	2.5	2.0	2.2
	Standard Deviation	-	0.0	0.0	1.9	-	1.9	-	1.7	1.7	1.9	1.2	1.5
	Median	-	2.0	2.0	2.0	-	2.0	-	1.0	1.0	2.0	2.0	2.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**
	Minimum	-	2	2	1	-	1	-	1	1	1	1	1
	Maximum	-	2	2	5	-	5	-	4	4	5	4	5
Pain	n	6	7	13	7	5	12	8	11	19	21	23	44
	Mean	1.7	1.7	1.7	1.7	2.2	1.9	1.9	2.5	2.2	1.8	2.2	2.0
	Standard Deviation	0.8	1.3	1.0	1.5	0.8	1.2	0.6	1.2	1.0	1.0	1.2	1.1
	Median	1.5	1.0	1.0	1.0	2.0	1.5	2.0	2.0	2.0	2.0	2.0	2.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	4	4	5	3	5	3	4	4	5	4	5
Any Sytemic Symptom	n	11	4	15	7	7	14	6	29	35	24	40	64
	Mean	1.6	1.0	1.5	1.4	2.0	1.7	1.5	1.2	1.3	1.5	1.4	1.4
	Standard Deviation	1.6	0.0	1.4	0.8	1.5	1.2	0.8	0.6	0.6	1.2	0.8	1.0
	Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	6	1	6	3	5	5	3	3	3	6	5	6
Arthralgia	n	1	-	1	1	-	1	-	3	3	2	3	5
	Mean	1.0	-	1.0	2.0	-	2.0	-	1.0	1.0	1.5	1.0	1.2
	Standard Deviation	.	-	.	.	-	.	-	0.0	0.0	0.7	0.0	0.4
	Median	1.0	-	1.0	2.0	-	2.0	-	1.0	1.0	1.5	1.0	1.0
	Minimum	1	-	1	2	-	2	-	1	1	1	1	1
	Maximum	1	-	1	2	-	2	-	1	1	2	1	2
Fatigue	n	3	1	4	5	5	10	3	9	12	11	15	26
	Mean	1.7	1.0	1.5	1.4	2.0	1.7	2.0	1.4	1.6	1.6	1.6	1.6
	Standard Deviation	1.2	.	1.0	0.9	1.7	1.3	1.0	0.7	0.8	0.9	1.1	1.0
	Median	1.0	1.0	1.0	1.0	1.0	1.0	2.0	1.0	1.0	1.0	1.0	1.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**
	Minimum	1	1	1	1	1	1	1	1	1	1	1	1
	Maximum	3	1	3	3	5	5	3	3	3	3	5	5
Fever	n	-	-	-	-	-	-	-	1	1	-	1	1
	Mean	-	-	-	-	-	-	-	1.0	1.0	-	1.0	1.0
	Standard Deviation	-	-	-	-	-	-	-	.	.	-	.	.
	Median	-	-	-	-	-	-	-	1.0	1.0	-	1.0	1.0
	Minimum	-	-	-	-	-	-	-	1	1	-	1	1
	Maximum	-	-	-	-	-	-	-	1	1	-	1	1
Feverishness	n	-	-	-	-	-	-	1	4	5	1	4	5
	Mean	-	-	-	-	-	-	1.0	1.0	1.0	1.0	1.0	1.0
	Standard Deviation	-	-	-	-	-	-	.	0.0	0.0	.	0.0	0.0
	Median	-	-	-	-	-	-	1.0	1.0	1.0	1.0	1.0	1.0
	Minimum	-	-	-	-	-	-	1	1	1	1	1	1
	Maximum	-	-	-	-	-	-	1	1	1	1	1	1
Headache	n	3	2	5	1	-	1	-	4	4	4	6	10
	Mean	1.0	1.0	1.0	1.0	-	1.0	-	1.5	1.5	1.0	1.3	1.2
	Standard Deviation	0.0	0.0	0.0	.	-	.	-	1.0	1.0	0.0	0.8	0.6
	Median	1.0	1.0	1.0	1.0	-	1.0	-	1.0	1.0	1.0	1.0	1.0
	Minimum	1	1	1	1	-	1	-	1	1	1	1	1
	Maximum	1	1	1	1	-	1	-	3	3	1	3	3
Myalgia	n	4	1	5	-	2	2	2	7	9	6	10	16
	Mean	2.3	1.0	2.0	-	2.0	2.0	1.0	1.1	1.1	1.8	1.3	1.5
	Standard Deviation	2.5	.	2.2	-	1.4	1.4	0.0	0.4	0.3	2.0	0.7	1.3
	Median	1.0	1.0	1.0	-	2.0	2.0	1.0	1.0	1.0	1.0	1.0	1.0

		25 µg mRNA-1273 (N=10)			50 µg mRNA-1273 (N=10)			100 µg mRNA-1273 (N=10)			All Subjects (N=30)		
Variable	**Statistic**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**	**Dose1**	**Dose2**	**All**
	Minimum	1	1	1	-	1	1	1	1	1	1	1	1
	Maximum	6	1	6	-	3	3	1	2	2	6	3	6
Nausea	n	-	-	-	-	-	-	-	1	1	-	1	1
	Mean	-	-	-	-	-	-	-	1.0	1.0	-	1.0	1.0
	Standard Deviation	-	-	-	-	-	-	-	.	.	-	.	.
	Median	-	-	-	-	-	-	-	1.0	1.0	-	1.0	1.0
	Minimum	-	-	-	-	-	-	-	1	1	-	1	1
	Maximum	-	-	-	-	-	-	-	1	1	-	1	1
n=number of solicited adverse events													

TABLE 87:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 25 µg mRNA-1273 18-55 years (N=15)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	24	4	-
	Moderate	2	1	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	2	-	-
	Moderate	1	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	6	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	1	-	-
	Moderate	1	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	8	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	1	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	2	1	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	2	2	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 88:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 50 µg mRNA-1273 18-55 years (N=15)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	14	6	-
	Moderate	3	1	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	1	1	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	1	-	-
	Moderate	2	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	2	1	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	1	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	2	2	-
	Moderate	1	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 89:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 100 µg mRNA-1273 18-55 years (N=15)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	14	8	-
	Moderate	4	2	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	2	-	-
	Moderate	-	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	3	3	-
	Moderate	-	1	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	-	-	-
	Moderate	2	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	2	-	-
	Moderate	1	-	-
	Severe	-	-	-
Investigations	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	2	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	2	1	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 90:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 250 µg mRNA-1273 18-55 years (N=15)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	15	9	-
	Moderate	6	8	-
	Severe	-	2	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	3	2	-
	Moderate	-	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	1	2	-
	Moderate	-	2	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	1	-	-
	Moderate	1	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	1	-
	Moderate	1	2	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	1	-
	Moderate	1	1	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	-	-
	Moderate	3	-	-
	Severe	-	2	-
Psychiatric Disorders	**Mild**	1	1	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	2	1	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	-	2	-
	Severe	-	-	-
Vascular Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 91:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 18-55 years (N=60)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	67	27	-
	Moderate	15	12	-
	Severe	-	2	-
Blood And Lymphatic System Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	4	1	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	2	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	8	2	-
	Moderate	3	4	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	12	6	-
	Moderate	-	3	-
	Severe	-	-	-
Immune System Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	3	-	-
	Moderate	4	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	12	-	-
	Moderate	1	-	-
	Severe	-	-	-
Investigations	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	3	-
	Moderate	1	2	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	4	3	-
	Moderate	1	1	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	3	-	-
	Moderate	3	-	-
	Severe	-	2	-
Psychiatric Disorders	**Mild**	1	1	-
	Moderate	1	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	3	1	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	7	4	-
	Moderate	1	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	3	2	-
	Moderate	-	2	-
	Severe	-	-	-
Vascular Disorders	**Mild**	3	1	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 92:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 25 µg mRNA-1273 56-70 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	6	1	-
	Moderate	5	1	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	-	-	-
	Moderate	2	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	1	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	2	-	-
	Moderate	1	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 93:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 50 µg mRNA-1273 56-70 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	4	-	-
	Moderate	2	1	-
	Severe	1	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	-	-	-
	Moderate	-	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	1	-	-
Injury, Poisoning And Procedural Complications	**Mild**	2	-	-
	Moderate	1	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 94:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 100 µg mRNA-1273 56-70 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	5	1	-
	Moderate	4	-	-
	Severe	1	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	1	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	1	-	-
	Moderate	1	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	2	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 95:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 56-70 years (N=30)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	15	2	-
	Moderate	11	2	-
	Severe	2	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	1	-	-
	Moderate	-	1	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	-	-	-
	Moderate	3	-	-
	Severe	1	-	-
Injury, Poisoning And Procedural Complications	**Mild**	3	-	-
	Moderate	3	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	1	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	1	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	1	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	3	-	-
	Moderate	1	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	2	-	-
	Moderate	1	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	2	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 96:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 25 µg mRNA-1273 ≥71 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	15	11	-
	Moderate	2	-	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	1	4	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	8	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	2	-	-
	Moderate	2	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	2	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	3	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	1	2	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 97:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 50 µg mRNA-1273 ≥71 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Mild	7	-	-
	Moderate	-	-	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	Mild	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	Mild	3	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	Mild	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	Mild	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 98:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 100 µg mRNA-1273 ≥71 years (N=10)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	21	3	-
	Moderate	-	-	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	5	1	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	7	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	-	1	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	4	1	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 99:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – ≥71 years (N=30)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	43	14	-
	Moderate	2	-	-
	Severe	-	-	-
Blood And Lymphatic System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Cardiac Disorders	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Ear And Labyrinth Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Eye Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Gastrointestinal Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
General Disorders And Administration Site Conditions	**Mild**	7	5	-
	Moderate	-	-	-
	Severe	-	-	-
Immune System Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Infections And Infestations	**Mild**	2	-	-
	Moderate	-	-	-
	Severe	-	-	-
Injury, Poisoning And Procedural Complications	**Mild**	18	-	-
	Moderate	-	-	-
	Severe	-	-	-
Investigations	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Metabolism And Nutrition Disorders	**Mild**	-	-	-
	Moderate	-	-	-

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Severe	-	-	-
Musculoskeletal And Connective Tissue Disorders	**Mild**	3	-	-
	Moderate	2	-	-
	Severe	-	-	-
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Nervous System Disorders	**Mild**	1	3	-
	Moderate	-	-	-
	Severe	-	-	-
Psychiatric Disorders	**Mild**	-	3	-
	Moderate	-	-	-
	Severe	-	-	-
Reproductive System And Breast Disorders	**Mild**	-	-	-
	Moderate	-	-	-
	Severe	-	-	-
Respiratory, Thoracic And Mediastinal Disorders	**Mild**	1	-	-
	Moderate	-	-	-
	Severe	-	-	-
Skin And Subcutaneous Tissue Disorders	**Mild**	5	3	-
	Moderate	-	-	-
	Severe	-	-	-
Vascular Disorders	**Mild**	3	-	-
	Moderate	-	-	-
	Severe	-	-	-

TABLE 100:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 18-55 years (N=15)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	31	28	3	-	26	5	-
Gastrointestinal disorders	**Any PT**	4	2	2	-	3	1	-
	Flatulence	1	1	-	-	1	-	-
	Vomiting	3	1	2	-	2	1	-
General disorders and administration site conditions	**Any PT**	6	6	-	-	6	-	-
	Fatigue	1	1	-	-	1	-	-
	Injection site irritation	1	1	-	-	1	-	-
	Vessel puncture site bruise	4	4	-	-	4	-	-
Infections and infestations	**Any PT**	2	1	1	-	2	-	-
	Hordeolum	1	-	1	-	1	-	-
	Pustule	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	**Any PT**	8	8	-	-	8	-	-
	Contusion	3	3	-	-	3	-	-
	Muscle strain	2	2	-	-	2	-	-
	Skin abrasion	1	1	-	-	1	-	-
	Skin laceration	1	1	-	-	1	-	-
	Wound	1	1	-	-	1	-	-
Musculoskeletal and connective tissue disorders	**Any PT**	2	2	-	-	1	1	-
	Muscular weakness	1	1	-	-	-	1	-
	Pain in jaw	1	1	-	-	1	-	-
Nervous system disorders	**Presyncope**	1	1	-	-	1	-	-
	Any PT	3	3	-	-	2	1	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Respiratory, thoracic and mediastinal disorders	**Dyspnoea exertional**	1	1	-	-	1	-	-
	Oropharyngeal pain	2	2	-	-	1	1	-
Skin and subcutaneous tissue disorders	**Any PT**	4	4	-	-	2	2	-
	Dermatitis contact	1	1	-	-	1	-	-
	Erythema	1	1	-	-	1	-	-
	Petechiae	1	1	-	-	-	1	-
	Urticaria	1	1	-	-	-	1	-
Vascular disorders	**Systolic hypertension**	1	1	-	-	1	-	-

TABLE 101:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 18-55 years (N=15)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	24	20	4	-	17	7	-
Blood and lymphatic system disorders	**Lymphadenopathy**	1	1	-	-	-	1	-
Cardiac disorders	**Bradycardia**	2	2	-	-	1	1	-
Ear and labyrinth disorders	**Vertigo**	1	1	-	-	1	-	-
Gastrointestinal disorders	**Any PT**	4	1	3	-	3	1	-
	Abdominal pain	1	-	1	-	1	-	-
	Diarrhoea	1	-	1	-	-	1	-
	Dyspepsia	1	1	-	-	1	-	-
	Tooth impacted	1	-	1	-	1	-	-
General disorders and administration site conditions	**Any PT**	3	3	-	-	2	1	-
	Vaccination site movement impairment	1	1	-	-	-	1	-
	Vessel puncture site bruise	1	1	-	-	1	-	-
	Vessel puncture site haemorrhage	1	1	-	-	1	-	-
Immune system disorders	**Seasonal allergy**	1	1	-	-	1	-	-
Infections and infestations	**Upper respiratory tract infection**	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	**Skin abrasion**	2	2	-	-	2	-	-
Investigations	**Blood glucose decreased**	1	1	-	-	1	-	-
Musculoskeletal and connective tissue disorders	**Any PT**	2	2	-	-	1	1	-
	Muscle spasms	1	1	-	-	-	1	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	**Preferred Term (PT)**	**Total Events (n)**	**Mild (n)**	**Moderate (n)**	**Severe (n)**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Myalgia	1	1	-	-	1	-	-
Respiratory, thoracic and mediastinal disorders	**Any PT**	5	4	1	-	3	2	-
	Nasal congestion	2	1	1	-	1	1	-
	Oropharyngeal pain	1	1	-	-	1	-	-
	Upper-airway cough syndrome	2	2	-	-	1	1	-
Skin and subcutaneous tissue disorders	**Rash**	1	1	-	-	1	-	-

TABLE 102:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 18-55 years (N=15)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	28	22	6	-	18	10	-
Cardiac disorders	**Bradycardia**	1	1	-	-	1	-	-
Eye disorders	**Eye irritation**	1	1	-	-	-	1	-
Gastrointestinal disorders	**Any PT**	3	2	1	-	2	1	-
	Abdominal discomfort	1	1	-	-	1	-	-
	Abdominal pain	1	-	1	-	-	1	-
	Faeces discoloured	1	1	-	-	1	-	-
General disorders and administration site conditions	**Any PT**	7	6	1	-	3	4	-
	Feeling jittery	1	-	1	-	-	1	-
	Injection site bruising	3	3	-	-	3	-	-
	Injection site pruritus	3	3	-	-	-	3	-
Infections and infestations	**Any PT**	2	-	2	-	2	-	-
	Gastroenteritis	1	-	1	-	1	-	-
	Infected cyst	1	-	1	-	1	-	-
Injury, poisoning and procedural complications	**Any PT**	3	2	1	-	3	-	-
	Muscle strain	2	1	1	-	2	-	-
	Thermal burn	1	1	-	-	1	-	-
Investigations	**Heart rate increased**	1	1	-	-	1	-	-
Metabolism and nutrition disorders	**Decreased appetite**	2	2	-	-	-	2	-
Musculoskeletal and connective tissue disorders	**Neck pain**	1	1	-	-	1	-	-
Nervous system disorders	**Dizziness**	1	1	-	-	1	-	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	**Preferred Term (PT)**	**Total Events (n)**	**Mild (n)**	**Moderate (n)**	**Severe (n)**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Psychiatric disorders	**Attention deficit hyperactivity disorder**	1	-	1	-	1	-	-
Reproductive system and breast disorders	**Breast pain**	1	1	-	-	1	-	-
Respiratory, thoracic and mediastinal disorders	**Any PT**	3	3	-	-	2	1	-
	Diaphragmatic spasm	1	1	-	-	-	1	-
	Nasal congestion	1	1	-	-	1	-	-
	Oropharyngeal pain	1	1	-	-	1	-	-
Vascular disorders	**Vasodilatation**	1	1	-	-	-	1	-

TABLE 103:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 250 µg mRNA-1273 18-55 years (N=15)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Any PT	40	24	14	2	21	19	-
Cardiac disorders	Bradycardia	2	2	-	-	2	-	-
Eye disorders	Scintillating scotoma	1	1	-	-	-	1	-
Gastrointestinal disorders	Any PT	6	5	1	-	3	3	-
	Abdominal discomfort	1	-	1	-	-	1	-
	Abdominal pain upper	1	1	-	-	-	1	-
	Anal fissure	1	1	-	-	1	-	-
	Dyspepsia	1	1	-	-	1	-	-
	Lip disorder	1	1	-	-	1	-	-
	Vomiting	1	1	-	-	-	1	-
General disorders and administration site conditions	Any PT	5	3	2	-	1	4	-
	Injection site erythema	2	1	1	-	-	2	-
	Injection site pruritus	1	1	-	-	-	1	-
	Malaise	1	-	1	-	-	1	-
	Vessel puncture site bruise	1	1	-	-	1	-	-
Infections and infestations	Any PT	2	1	1	-	2	-	-
	Epididymitis	1	-	1	-	1	-	-
	Urinary tract infection	1	1	-	-	1	-	-
Metabolism and nutrition disorders	Any PT	4	1	3	-	1	3	-
	Decreased appetite	3	1	2	-	-	3	-
	Hypoglycaemia	1	-	1	-	1	-	-
Musculoskeletal and connective tissue disorders	Any PT	4	2	2	-	2	2	-
	Arthralgia	1	1	-	-	1	-	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
	Muscle spasms	1	-	1	-	-	1	-
	Muscle strain	1	-	1	-	1	-	-
	Pain in extremity	1	1	-	-	-	1	-
Nervous system disorders	Any PT	6	1	3	2	4	2	-
	Dizziness	1	-	-	1	-	1	-
	Headache	4	1	3	-	4	-	-
	Syncope	1	-	-	1	-	1	-
Psychiatric disorders	Any PT	2	2	-	-	1	1	-
	Anxiety	1	1	-	-	-	1	-
	Insomnia	1	1	-	-	1	-	-
Reproductive system and breast disorders	Any PT	3	3	-	-	2	1	-
	Vaginal haemorrhage	1	1	-	-	-	1	-
	Vulvovaginal pruritus	2	2	-	-	2	-	-
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	1	1	-	-	1	-	-
Skin and subcutaneous tissue disorders	Any PT	2	-	2	-	-	2	-
	Hyperhidrosis	1	-	1	-	-	1	-
	Night sweats	1	-	1	-	-	1	-
Vascular disorders	Any PT	2	2	-	-	2	-	-
	Hypertension	1	1	-	-	1	-	-
	Hypotension	1	1	-	-	1	-	-

TABLE 104:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 18-55 years (N=60)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	123	94	27	2	82	41	-
Blood and lymphatic system disorders	**Lymphadenopathy**	1	1	-	-	-	1	-
Cardiac disorders	**Bradycardia**	5	5	-	-	4	1	-
Ear and labyrinth disorders	**Vertigo**	1	1	-	-	1	-	-
Eye disorders	**Any PT**	2	2	-	-	-	2	-
	Eye irritation	1	1	-	-	-	1	-
	Scintillating scotoma	1	1	-	-	-	1	-
Gastrointestinal disorders	**Any PT**	17	10	7	-	11	6	-
	Abdominal discomfort	2	1	1	-	1	1	-
	Abdominal pain	2	-	2	-	1	1	-
	Abdominal pain upper	1	1	-	-	-	1	-
	Anal fissure	1	1	-	-	1	-	-
	Diarrhoea	1	-	1	-	-	1	-
	Dyspepsia	2	2	-	-	2	-	-
	Faeces discoloured	1	1	-	-	1	-	-
	Flatulence	1	1	-	-	1	-	-
	Lip disorder	1	1	-	-	1	-	-
	Tooth impacted	1	-	1	-	1	-	-
	Vomiting	4	2	2	-	2	2	-
General disorders and administration site conditions	**Any PT**	21	18	3	-	12	9	-
	Fatigue	1	1	-	-	1	-	-
	Feeling jittery	1	-	1	-	-	1	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
	Injection site bruising	3	3	-	-	3	-	-
	Injection site erythema	2	1	1	-	-	2	-
	Injection site irritation	1	1	-	-	1	-	-
	Injection site pruritus	4	4	-	-	-	4	-
	Malaise	1	-	1	-	-	1	-
	Vaccination site movement impairment	1	1	-	-	-	1	-
	Vessel puncture site bruise	6	6	-	-	6	-	-
	Vessel puncture site haemorrhage	1	1	-	-	1	-	-
Immune system disorders	Seasonal allergy	1	1	-	-	1	-	-
Infections and infestations	Any PT	7	3	4	-	7	-	-
	Epididymitis	1	-	1	-	1	-	-
	Gastroenteritis	1	-	1	-	1	-	-
	Hordeolum	1	-	1	-	1	-	-
	Infected cyst	1	-	1	-	1	-	-
	Pustule	1	1	-	-	1	-	-
	Upper respiratory tract infection	1	1	-	-	1	-	-
	Urinary tract infection	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	Any PT	13	12	1	-	13	-	-
	Contusion	3	3	-	-	3	-	-
	Muscle strain	4	3	1	-	4	-	-
	Skin abrasion	3	3	-	-	3	-	-
	Skin laceration	1	1	-	-	1	-	-
	Thermal burn	1	1	-	-	1	-	-
	Wound	1	1	-	-	1	-	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Investigations	**Any PT**	2	2	-	-	2	-	-
	Blood glucose decreased	1	1	-	-	1	-	-
	Heart rate increased	1	1	-	-	1	-	-
Metabolism and nutrition disorders	**Any PT**	6	3	3	-	1	5	-
	Decreased appetite	5	3	2	-	-	5	-
	Hypoglycaemia	1	-	1	-	1	-	-
Musculoskeletal and connective tissue disorders	**Any PT**	9	7	2	-	5	4	-
	Arthralgia	1	1	-	-	1	-	-
	Muscle spasms	2	1	1	-	-	2	-
	Muscle strain	1	-	1	-	1	-	-
	Muscular weakness	1	1	-	-	-	1	-
	Myalgia	1	1	-	-	1	-	-
	Neck pain	1	1	-	-	1	-	-
	Pain in extremity	1	1	-	-	-	1	-
	Pain in jaw	1	1	-	-	1	-	-
Nervous system disorders	**Any PT**	8	3	3	2	6	2	-
	Dizziness	2	1	-	1	1	1	-
	Headache	4	1	3	-	4	-	-
	Presyncope	1	1	-	-	1	-	-
	Syncope	1	-	-	1	-	1	-
Psychiatric disorders	**Any PT**	3	2	1	-	2	1	-
	Anxiety	1	1	-	-	-	1	-
	Attention deficit hyperactivity disorder	1	-	1	-	1	-	-
	Insomnia	1	1	-	-	1	-	-
Reproductive system and breast disorders	**Any PT**	4	4	-	-	3	1	-
	Breast pain	1	1	-	-	1	-	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
	Vaginal haemorrhage	1	1	-	-	-	1	-
	Vulvovaginal pruritus	2	2	-	-	2	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	12	11	1	-	8	4	-
	Diaphragmatic spasm	1	1	-	-	-	1	-
	Dyspnoea exertional	1	1	-	-	1	-	-
	Nasal congestion	3	2	1	-	2	1	-
	Oropharyngeal pain	5	5	-	-	4	1	-
	Upper-airway cough syndrome	2	2	-	-	1	1	-
Skin and subcutaneous tissue disorders	Any PT	7	5	2	-	3	4	-
	Dermatitis contact	1	1	-	-	1	-	-
	Erythema	1	1	-	-	1	-	-
	Hyperhidrosis	1	-	1	-	-	1	-
	Night sweats	1	-	1	-	-	1	-
	Petechiae	1	1	-	-	-	1	-
	Rash	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	-

TABLE 105:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 56-70 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	13	7	6	-	11	2	-
General disorders and administration site conditions	**Injection site bruising**	2	2	-	-	2	-	-
Infections and infestations	**Onychomycosis**	1	-	1	-	1	-	-
Injury, poisoning and procedural complications	**Any PT**	2	-	2	-	2	-	-
	Exposure via inhalation	1	-	1	-	1	-	-
	Limb injury	1	-	1	-	1	-	-
Investigations	**Bone density decreased**	1	-	1	-	1	-	-
Metabolism and nutrition disorders	**Decreased appetite**	1	-	1	-	-	1	-
Musculoskeletal and connective tissue disorders	**Pain in extremity**	1	1	-	-	1	-	-
Nervous system disorders	**Any PT**	3	2	1	-	3	-	-
	Headache	1	1	-	-	1	-	-
	Sciatica	2	1	1	-	2	-	-
Psychiatric disorders	**Insomnia**	1	1	-	-	-	1	-
Respiratory, thoracic and mediastinal disorders	**Oropharyngeal pain**	1	1	-	-	1	-	-

TABLE 106:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 56-70 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	8	4	3	1	7	1	-
Cardiac disorders	**Bradycardia**	2	2	-	-	2	-	-
Gastrointestinal disorders	**Abdominal discomfort**	1	-	1	-	-	1	-
Infections and infestations	**Any PT**	2	-	1	1	2	-	-
	Urinary tract infection	1	-	1	-	1	-	-
	Viral infection	1	-	-	1	1	-	-
Injury, poisoning and procedural complications	**Any PT**	3	2	1	-	3	-	-
	Muscle strain	1	1	-	-	1	-	-
	Skin laceration	1	1	-	-	1	-	-
	Tooth fracture	1	-	1	-	1	-	-

TABLE 107:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 56-70 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Any PT	11	6	4	1	10	1	-
Ear and labyrinth disorders	Vertigo	1	1	-	-	-	1	-
Gastrointestinal disorders	Haemorrhoids	1	1	-	-	1	-	-
Infections and infestations	Paronychia	1	-	1	-	1	-	-
Injury, poisoning and procedural complications	Arthropod sting	1	1	-	-	1	-	-
Metabolism and nutrition disorders	Hypoglycaemia	1	-	-	1	1	-	-
Nervous system disorders	Dizziness	1	1	-	-	1	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	2	1	1	-	2	-	-
	Nasal congestion	1	-	1	-	1	-	-
	Oropharyngeal pain	1	1	-	-	1	-	-
Skin and subcutaneous tissue disorders	Any PT	2	-	2	-	2	-	-
	Dermatitis contact	1	-	1	-	1	-	-
	Rash maculo-papular	1	-	1	-	1	-	-
Vascular disorders	Systolic hypertension	1	1	-	-	1	-	-

TABLE 108:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 56-70 years (N=30)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Any PT	32	17	13	2	28	4	-
Cardiac disorders	Bradycardia	2	2	-	-	2	-	-
Ear and labyrinth disorders	Vertigo	1	1	-	-	-	1	-
Gastrointestinal disorders	Any PT	2	1	1	-	1	1	-
	Abdominal discomfort	1	-	1	-	-	1	-
	Haemorrhoids	1	1	-	-	1	-	-
General disorders and administration site conditions	Injection site bruising	2	2	-	-	2	-	-
Infections and infestations	Any PT	4	-	3	1	4	-	-
	Onychomycosis	1	-	1	-	1	-	-
	Paronychia	1	-	1	-	1	-	-
	Urinary tract infection	1	-	1	-	1	-	-
	Viral infection	1	-	-	1	1	-	-
Injury, poisoning and procedural complications	Any PT	6	3	3	-	6	-	-
	Arthropod sting	1	1	-	-	1	-	-
	Exposure via inhalation	1	-	1	-	1	-	-
	Limb injury	1	-	1	-	1	-	-
	Muscle strain	1	1	-	-	1	-	-
	Skin laceration	1	1	-	-	1	-	-
	Tooth fracture	1	-	1	-	1	-	-
Investigations	Bone density decreased	1	-	1	-	1	-	-
Metabolism and nutrition disorders	Any PT	2	-	1	1	1	1	-
	Decreased appetite	1	-	1	-	-	1	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
	Hypoglycaemia	1	-	-	1	1	-	-
Musculoskeletal and connective tissue disorders	**Pain in extremity**	1	1	-	-	1	-	-
Nervous system disorders	**Any PT**	4	3	1	-	4	-	-
	Dizziness	1	1	-	-	1	-	-
	Headache	1	1	-	-	1	-	-
	Sciatica	2	1	1	-	2	-	-
Psychiatric disorders	**Insomnia**	1	1	-	-	-	1	-
Respiratory, thoracic and mediastinal disorders	**Any PT**	3	2	1	-	3	-	-
	Nasal congestion	1	-	1	-	1	-	-
	Oropharyngeal pain	2	2	-	-	2	-	-
Skin and subcutaneous tissue disorders	**Any PT**	2	-	2	-	2	-	-
	Dermatitis contact	1	-	1	-	1	-	-
	Rash maculo-papular	1	-	1	-	1	-	-
Vascular disorders	**Systolic hypertension**	1	1	-	-	1	-	-

TABLE 109:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 ≥71 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Any PT	28	26	2	-	17	11	-
Cardiac disorders	Bradycardia	1	1	-	-	1	-	-
General disorders and administration site conditions	Any PT	5	5	-	-	1	4	-
	Energy increased	2	2	-	-	-	2	-
	Fatigue	1	1	-	-	-	1	-
	Injection site bruising	1	1	-	-	1	-	-
	Injection site pruritus	1	1	-	-	-	1	-
Infections and infestations	Pustule	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	Any PT	8	8	-	-	8	-	-
	Arthropod bite	1	1	-	-	1	-	-
	Limb injury	1	1	-	-	1	-	-
	Procedural pain	1	1	-	-	1	-	-
	Skin abrasion	3	3	-	-	3	-	-
	Sunburn	1	1	-	-	1	-	-
	Thermal burn	1	1	-	-	1	-	-
Musculoskeletal and connective tissue disorders	Any PT	4	2	2	-	4	-	-
	Arthritis	1	-	1	-	1	-	-
	Joint swelling	1	1	-	-	1	-	-
	Muscle tightness	1	1	-	-	1	-	-
	Musculoskeletal chest pain	1	-	1	-	1	-	-
Nervous system disorders	Any PT	3	3	-	-	1	2	-
	Dizziness	2	2	-	-	1	1	-
	Visual field defect	1	1	-	-	-	1	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	**Preferred Term (PT)**	**Total Events (n)**	**Mild (n)**	**Moderate (n)**	**Severe (n)**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Psychiatric disorders	**Any PT**	3	3	-	-	-	3	-
	Anxiety	1	1	-	-	-	1	-
	Sleep disorder	2	2	-	-	-	2	-
Skin and subcutaneous tissue disorders	**Any PT**	3	3	-	-	1	2	-
	Night sweats	1	1	-	-	-	1	-
	Pruritus	1	1	-	-	-	1	-
	Skin irritation	1	1	-	-	1	-	-

TABLE 110:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 ≥71 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	7	7	-	-	7	-	-
General disorders and administration site conditions	**Injection site bruising**	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	**Any PT**	3	3	-	-	3	-	-
	Arthropod bite	1	1	-	-	1	-	-
	Injury	2	2	-	-	2	-	-
Respiratory, thoracic and mediastinal disorders	**Oropharyngeal pain**	1	1	-	-	1	-	-
Vascular disorders	**Hypertension**	2	2	-	-	2	-	-

TABLE 111:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 ≥71 years (N=10)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	**Any PT**	24	24	-	-	21	3	-
Cardiac disorders	**Bradycardia**	1	1	-	-	1	-	-
General disorders and administration site conditions	**Any PT**	6	6	-	-	5	1	-
	Injection site bruising	1	1	-	-	1	-	-
	Injection site erythema	1	1	-	-	-	1	-
	Vessel puncture site bruise	4	4	-	-	4	-	-
Infections and infestations	**Urinary tract infection**	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	**Any PT**	7	7	-	-	7	-	-
	Contusion	3	3	-	-	3	-	-
	Skin abrasion	3	3	-	-	3	-	-
	Tooth fracture	1	1	-	-	1	-	-
Musculoskeletal and connective tissue disorders	**Myalgia**	1	1	-	-	1	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**Squamous cell carcinoma**	1	1	-	-	1	-	-
Nervous system disorders	**Dizziness**	1	1	-	-	-	1	-
Skin and subcutaneous tissue disorders	**Any PT**	5	5	-	-	4	1	-
	Blister	1	1	-	-	1	-	-
	Dermatitis	1	1	-	-	1	-	-
	Dermatitis contact	1	1	-	-	1	-	-
	Night sweats	1	1	-	-	-	1	-
	Rash	1	1	-	-	1	-	-
Vascular disorders	**Systolic hypertension**	1	1	-	-	1	-	-

TABLE 112:
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – ≥71 years (N=30)

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Any SOC	Any PT	59	57	2	-	45	14	-
Cardiac disorders	Bradycardia	2	2	-	-	2	-	-
General disorders and administration site conditions	Any PT	12	12	-	-	7	5	-
	Energy increased	2	2	-	-	-	2	-
	Fatigue	1	1	-	-	-	1	-
	Injection site bruising	3	3	-	-	3	-	-
	Injection site erythema	1	1	-	-	-	1	-
	Injection site pruritus	1	1	-	-	-	1	-
	Vessel puncture site bruise	4	4	-	-	4	-	-
Infections and infestations	Any PT	2	2	-	-	2	-	-
	Pustule	1	1	-	-	1	-	-
	Urinary tract infection	1	1	-	-	1	-	-
Injury, poisoning and procedural complications	Any PT	18	18	-	-	18	-	-
	Arthropod bite	2	2	-	-	2	-	-
	Contusion	3	3	-	-	3	-	-
	Injury	2	2	-	-	2	-	-
	Limb injury	1	1	-	-	1	-	-
	Procedural pain	1	1	-	-	1	-	-
	Skin abrasion	6	6	-	-	6	-	-
	Sunburn	1	1	-	-	1	-	-
	Thermal burn	1	1	-	-	1	-	-
	Tooth fracture	1	1	-	-	1	-	-
	Any PT	5	3	2	-	5	-	-

			Severity			Relationship to Study Vaccination		
System Organ Class (SOC)	Preferred Term (PT)	Total Events (n)	Mild (n)	Moderate (n)	Severe (n)	Not Related (n)	Related (n)	Not Yet Determined (n)
Musculoskeletal and connective tissue disorders	**Arthritis**	1	-	1	-	1	-	-
	Joint swelling	1	1	-	-	1	-	-
	Muscle tightness	1	1	-	-	1	-	-
	Musculoskeletal chest pain	1	-	1	-	1	-	-
	Myalgia	1	1	-	-	1	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**Squamous cell carcinoma**	1	1	-	-	1	-	-
Nervous system disorders	**Any PT**	4	4	-	-	1	3	-
	Dizziness	3	3	-	-	1	2	-
	Visual field defect	1	1	-	-	-	1	-
Psychiatric disorders	**Any PT**	3	3	-	-	-	3	-
	Anxiety	1	1	-	-	-	1	-
	Sleep disorder	2	2	-	-	-	2	-
Respiratory, thoracic and mediastinal disorders	**Oropharyngeal pain**	1	1	-	-	1	-	-
Skin and subcutaneous tissue disorders	**Any PT**	8	8	-	-	5	3	-
	Blister	1	1	-	-	1	-	-
	Dermatitis	1	1	-	-	1	-	-
	Dermatitis contact	1	1	-	-	1	-	-
	Night sweats	2	2	-	-	-	2	-
	Pruritus	1	1	-	-	-	1	-
	Rash	1	1	-	-	1	-	-
	Skin irritation	1	1	-	-	1	-	-
Vascular disorders	**Any PT**	3	3	-	-	3	-	-
	Hypertension	2	2	-	-	2	-	-
	Systolic hypertension	1	1	-	-	1	-	-

TABLE 113:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 18-55 years (N=15)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	12	80	12	80	3	20	-	-	11	73	4	27
Gastrointestinal disorders	Any PT	4	27	2	13	2	13	-	-	3	20	1	7
	Flatulence	1	7	1	7	-	-	-	-	1	7	-	-
	Vomiting	3	20	1	7	2	13	-	-	2	13	1	7
General disorders and administration site conditions	Any PT	4	27	4	27	-	-	-	-	4	27	-	-
	Fatigue	1	7	1	7	-	-	-	-	1	7	-	-
	Injection site irritation	1	7	1	7	-	-	-	-	1	7	-	-
	Vessel puncture site bruise	2	13	2	13	-	-	-	-	2	13	-	-
Infections and infestations	Any PT	2	13	1	7	1	7	-	-	2	13	-	-
	Hordeolum	1	7	-	-	1	7	-	-	1	7	-	-
	Pustule	1	7	1	7	-	-	-	-	1	7	-	-
Injury, poisoning and procedural complications	Any PT	5	33	5	33	-	-	-	-	5	33	-	-
	Contusion	3	20	3	20	-	-	-	-	3	20	-	-
	Muscle strain	2	13	2	13	-	-	-	-	2	13	-	-
	Skin abrasion	1	7	1	7	-	-	-	-	1	7	-	-
	Skin laceration	1	7	1	7	-	-	-	-	1	7	-	-
	Wound	1	7	1	7	-	-	-	-	1	7	-	-
Musculoskeletal and connective tissue disorders	Any PT	2	13	2	13	-	-	-	-	1	7	1	7
	Muscular weakness	1	7	1	7	-	-	-	-	-	-	1	7
	Pain in jaw	1	7	1	7	-	-	-	-	1	7	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Nervous system disorders	Presyncope	1	7	1	7	-	-	-	-	1	7	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	2	13	2	13	-	-	-	-	2	13	1	7
	Dyspnoea exertional	1	7	1	7	-	-	-	-	1	7	-	-
	Oropharyngeal pain	1	7	1	7	-	-	-	-	1	7	1	7
Skin and subcutaneous tissue disorders	Any PT	4	27	4	27	-	-	-	-	2	13	2	13
	Dermatitis contact	1	7	1	7	-	-	-	-	1	7	-	-
	Erythema	1	7	1	7	-	-	-	-	1	7	-	-
	Petechiae	1	7	1	7	-	-	-	-	-	-	1	7
	Urticaria	1	7	1	7	-	-	-	-	-	-	1	7
Vascular disorders	Systolic hypertension	1	7	1	7	-	-	-	-	1	7	-	-

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 114:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 18-55 years (N=15)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	10	67	10	67	3	20	-	-	8	53	6	40
Blood and lymphatic system disorders	Lymphadenopathy	1	7	1	7	-	-	-	-	-	-	1	7
Cardiac disorders	Bradycardia	2	13	2	13	-	-	-	-	1	7	1	7
Ear and labyrinth disorders	Vertigo	1	7	1	7	-	-	-	-	1	7	-	-
Gastrointestinal disorders	Any PT	3	20	1	7	2	13	-	-	3	20	1	7
	Abdominal pain	1	7	-	-	1	7	-	-	1	7	-	-
	Diarrhoea	1	7	-	-	1	7	-	-	-	-	1	7
	Dyspepsia	1	7	1	7	-	-	-	-	1	7	-	-
	Tooth impacted	1	7	-	-	1	7	-	-	1	7	-	-
General disorders and administration site conditions	Any PT	3	20	3	20	-	-	-	-	2	13	1	7
	Vaccination site movement impairment	1	7	1	7	-	-	-	-	-	-	1	7
	Vessel puncture site bruise	1	7	1	7	-	-	-	-	1	7	-	-
	Vessel puncture site haemorrhage	1	7	1	7	-	-	-	-	1	7	-	-
Immune system disorders	Seasonal allergy	1	7	1	7	-	-	-	-	1	7	-	-
Infections and infestations	Upper respiratory tract infection	1	7	1	7	-	-	-	-	1	7	-	-
Injury, poisoning and procedural complications	Skin abrasion	2	13	2	13	-	-	-	-	2	13	-	-
Investigations	Blood glucose decreased	1	7	1	7	-	-	-	-	1	7	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Musculoskeletal and connective tissue disorders	**Any PT**	2	13	2	13	-	-	-	-	1	7	1	7
	Muscle spasms	1	7	1	7	-	-	-	-	-	-	1	7
	Myalgia	1	7	1	7	-	-	-	-	1	7	-	-
Respiratory, thoracic and mediastinal disorders	**Any PT**	2	13	2	13	1	7	-	-	2	13	1	7
	Nasal congestion	1	7	1	7	1	7	-	-	1	7	1	7
	Oropharyngeal pain	1	7	1	7	-	-	-	-	1	7	-	-
	Upper-airway cough syndrome	1	7	1	7	-	-	-	-	1	7	1	7
Skin and subcutaneous tissue disorders	**Rash**	1	7	1	7	-	-	-	-	1	7	-	-
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 115:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 18-55 years (N=15)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	11	73	9	60	5	33	-	-	9	60	3	20
Cardiac disorders	Bradycardia	1	7	1	7	-	-	-	-	1	7	-	-
Eye disorders	Eye irritation	1	7	1	7	-	-	-	-	-	-	1	7
Gastrointestinal disorders	Any PT	2	13	1	7	1	7	-	-	1	7	1	7
	Abdominal discomfort	1	7	1	7	-	-	-	-	1	7	-	-
	Abdominal pain	1	7	-	-	1	7	-	-	-	-	1	7
	Faeces discoloured	1	7	1	7	-	-	-	-	1	7	-	-
General disorders and administration site conditions	Any PT	4	27	4	27	1	7	-	-	3	20	2	13
	Feeling jittery	1	7	-	-	1	7	-	-	-	-	1	7
	Injection site bruising	3	20	3	20	-	-	-	-	3	20	-	-
	Injection site pruritus	2	13	2	13	-	-	-	-	-	-	2	13
Infections and infestations	Any PT	2	13	-	-	2	13	-	-	2	13	-	-
	Gastroenteritis	1	7	-	-	1	7	-	-	1	7	-	-
	Infected cyst	1	7	-	-	1	7	-	-	1	7	-	-
Injury, poisoning and procedural complications	Any PT	3	20	2	13	1	7	-	-	3	20	-	-
	Muscle strain	2	13	1	7	1	7	-	-	2	13	-	-
	Thermal burn	1	7	1	7	-	-	-	-	1	7	-	-
Investigations	Heart rate increased	1	7	1	7	-	-	-	-	1	7	-	-
Metabolism and nutrition disorders	Decreased appetite	1	7	1	7	-	-	-	-	-	-	1	7
Musculoskeletal and connective tissue disorders	Neck pain	1	7	1	7	-	-	-	-	1	7	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Nervous system disorders	Dizziness	1	7	1	7	-	-	-	-	1	7	-	-
Psychiatric disorders	Attention deficit hyperactivity disorder	1	7	-	-	1	7	-	-	1	7	-	-
Reproductive system and breast disorders	Breast pain	1	7	1	7	-	-	-	-	1	7	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	3	20	3	20	-	-	-	-	2	13	1	7
	Diaphragmatic spasm	1	7	1	7	-	-	-	-	-	-	1	7
	Nasal congestion	1	7	1	7	-	-	-	-	1	7	-	-
	Oropharyngeal pain	1	7	1	7	-	-	-	-	1	7	-	-
Vascular disorders	Vasodilatation	1	7	1	7	-	-	-	-	-	-	1	7

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 116:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 250 µg mRNA-1273 18-55 years (N=15)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	11	73	7	47	8	53	1	7	8	53	7	47
Cardiac disorders	Bradycardia	1	7	1	7	-	-	-	-	1	7	-	-
Eye disorders	Scintillating scotoma	1	7	1	7	-	-	-	-	-	-	1	7
Gastrointestinal disorders	Any PT	6	40	5	33	1	7	-	-	3	20	3	20
	Abdominal discomfort	1	7	-	-	1	7	-	-	-	-	1	7
	Abdominal pain upper	1	7	1	7	-	-	-	-	-	-	1	7
	Anal fissure	1	7	1	7	-	-	-	-	1	7	-	-
	Dyspepsia	1	7	1	7	-	-	-	-	1	7	-	-
	Lip disorder	1	7	1	7	-	-	-	-	1	7	-	-
	Vomiting	1	7	1	7	-	-	-	-	-	-	1	7
General disorders and administration site conditions	Any PT	3	20	2	13	2	13	-	-	1	7	3	20
	Injection site erythema	2	13	1	7	1	7	-	-	-	-	2	13
	Injection site pruritus	1	7	1	7	-	-	-	-	-	-	1	7
	Malaise	1	7	-	-	1	7	-	-	-	-	1	7
	Vessel puncture site bruise	1	7	1	7	-	-	-	-	1	7	-	-
Infections and infestations	Any PT	2	13	1	7	1	7	-	-	2	13	-	-
	Epididymitis	1	7	-	-	1	7	-	-	1	7	-	-
	Urinary tract infection	1	7	1	7	-	-	-	-	1	7	-	-
Metabolism and nutrition disorders	Any PT	4	27	1	7	3	20	-	-	1	7	3	20
	Decreased appetite	3	20	1	7	2	13	-	-	-	-	3	20
	Hypoglycaemia	1	7	-	-	1	7	-	-	1	7	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Musculoskeletal and connective tissue disorders	**Any PT**	4	27	2	13	2	13	-	-	2	13	2	13
	Arthralgia	1	7	1	7	-	-	-	-	1	7	-	-
	Muscle spasms	1	7	-	-	1	7	-	-	-	-	1	7
	Muscle strain	1	7	-	-	1	7	-	-	1	7	-	-
	Pain in extremity	1	7	1	7	-	-	-	-	-	-	1	7
Nervous system disorders	**Any PT**	3	20	1	7	1	7	1	7	2	13	1	7
	Dizziness	1	7	-	-	-	-	1	7	-	-	1	7
	Headache	2	13	1	7	1	7	-	-	2	13	-	-
	Syncope	1	7	-	-	-	-	1	7	-	-	1	7
Psychiatric disorders	**Any PT**	1	7	1	7	-	-	-	-	1	7	1	7
	Anxiety	1	7	1	7	-	-	-	-	-	-	1	7
	Insomnia	1	7	1	7	-	-	-	-	1	7	-	-
Reproductive system and breast disorders	**Any PT**	3	20	3	20	-	-	-	-	2	13	1	7
	Vaginal haemorrhage	1	7	1	7	-	-	-	-	-	-	1	7
	Vulvovaginal pruritus	2	13	2	13	-	-	-	-	2	13	-	-
Respiratory, thoracic and mediastinal disorders	**Oropharyngeal pain**	1	7	1	7	-	-	-	-	1	7	-	-
Skin and subcutaneous tissue disorders	**Any PT**	2	13	-	-	2	13	-	-	-	-	2	13
	Hyperhidrosis	1	7	-	-	1	7	-	-	-	-	1	7
	Night sweats	1	7	-	-	1	7	-	-	-	-	1	7
Vascular disorders	**Any PT**	2	13	2	13	-	-	-	-	2	13	-	-
	Hypertension	1	7	1	7	-	-	-	-	1	7	-	-
	Hypotension	1	7	1	7	-	-	-	-	1	7	-	-

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 117:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 18-55 years (N=60)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	44	73	38	63	19	32	1	2	36	60	20	33
Blood and lymphatic system disorders	Lymphadenopathy	1	2	1	2	-	-	-	-	-	-	1	2
Cardiac disorders	Bradycardia	4	7	4	7	-	-	-	-	3	5	1	2
Ear and labyrinth disorders	Vertigo	1	2	1	2	-	-	-	-	1	2	-	-
Eye disorders	Any PT	2	3	2	3	-	-	-	-	-	-	2	3
	Eye irritation	1	2	1	2	-	-	-	-	-	-	1	2
	Scintillating scotoma	1	2	1	2	-	-	-	-	-	-	1	2
Gastrointestinal disorders	Any PT	15	25	9	15	6	10	-	-	10	17	6	10
	Abdominal discomfort	2	3	1	2	1	2	-	-	1	2	1	2
	Abdominal pain	2	3	-	-	2	3	-	-	1	2	1	2
	Abdominal pain upper	1	2	1	2	-	-	-	-	-	-	1	2
	Anal fissure	1	2	1	2	-	-	-	-	1	2	-	-
	Diarrhoea	1	2	-	-	1	2	-	-	-	-	1	2
	Dyspepsia	2	3	2	3	-	-	-	-	2	3	-	-
	Faeces discoloured	1	2	1	2	-	-	-	-	1	2	-	-
	Flatulence	1	2	1	2	-	-	-	-	1	2	-	-
	Lip disorder	1	2	1	2	-	-	-	-	1	2	-	-
	Tooth impacted	1	2	-	-	1	2	-	-	1	2	-	-
	Vomiting	4	7	2	3	2	3	-	-	2	3	2	3
General disorders and administration site conditions	Any PT	14	23	13	22	3	5	-	-	10	17	6	10
	Fatigue	1	2	1	2	-	-	-	-	1	2	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
	Feeling jittery	1	2	-	-	1	2	-	-	-	-	1	2
	Injection site bruising	3	5	3	5	-	-	-	-	3	5	-	-
	Injection site erythema	2	3	1	2	1	2	-	-	-	-	2	3
	Injection site irritation	1	2	1	2	-	-	-	-	1	2	-	-
	Injection site pruritus	3	5	3	5	-	-	-	-	-	-	3	5
	Malaise	1	2	-	-	1	2	-	-	-	-	1	2
	Vaccination site movement impairment	1	2	1	2	-	-	-	-	-	-	1	2
	Vessel puncture site bruise	4	7	4	7	-	-	-	-	4	7	-	-
	Vessel puncture site haemorrhage	1	2	1	2	-	-	-	-	1	2	-	-
Immune system disorders	Seasonal allergy	1	2	1	2	-	-	-	-	1	2	-	-
Infections and infestations	Any PT	7	12	3	5	4	7	-	-	7	12	-	-
	Epididymitis	1	2	-	-	1	2	-	-	1	2	-	-
	Gastroenteritis	1	2	-	-	1	2	-	-	1	2	-	-
	Hordeolum	1	2	-	-	1	2	-	-	1	2	-	-
	Infected cyst	1	2	-	-	1	2	-	-	1	2	-	-
	Pustule	1	2	1	2	-	-	-	-	1	2	-	-
	Upper respiratory tract infection	1	2	1	2	-	-	-	-	1	2	-	-
	Urinary tract infection	1	2	1	2	-	-	-	-	1	2	-	-
Injury, poisoning and procedural complications	Any PT	10	17	9	15	1	2	-	-	10	17	-	-
	Contusion	3	5	3	5	-	-	-	-	3	5	-	-
	Muscle strain	4	7	3	5	1	2	-	-	4	7	-	-
	Skin abrasion	3	5	3	5	-	-	-	-	3	5	-	-
	Skin laceration	1	2	1	2	-	-	-	-	1	2	-	-

		Any Incidence		Severity						Relationship to Study Vaccination			
				Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
	Thermal burn	1	2	1	2	-	-	-	-	1	2	-	-
	Wound	1	2	1	2	-	-	-	-	1	2	-	-
Investigations	Any PT	2	3	2	3	-	-	-	-	2	3	-	-
	Blood glucose decreased	1	2	1	2	-	-	-	-	1	2	-	-
	Heart rate increased	1	2	1	2	-	-	-	-	1	2	-	-
Metabolism and nutrition disorders	Any PT	5	8	2	3	3	5	-	-	1	2	4	7
	Decreased appetite	4	7	2	3	2	3	-	-	-	-	4	7
	Hypoglycaemia	1	2	-	-	1	2	-	-	1	2	-	-
Musculoskeletal and connective tissue disorders	Any PT	9	15	7	12	2	3	-	-	5	8	4	7
	Arthralgia	1	2	1	2	-	-	-	-	1	2	-	-
	Muscle spasms	2	3	1	2	1	2	-	-	-	-	2	3
	Muscle strain	1	2	-	-	1	2	-	-	1	2	-	-
	Muscular weakness	1	2	1	2	-	-	-	-	-	-	1	2
	Myalgia	1	2	1	2	-	-	-	-	1	2	-	-
	Neck pain	1	2	1	2	-	-	-	-	1	2	-	-
	Pain in extremity	1	2	1	2	-	-	-	-	-	-	1	2
	Pain in jaw	1	2	1	2	-	-	-	-	1	2	-	-
Nervous system disorders	Any PT	5	8	3	5	1	2	1	2	4	7	1	2
	Dizziness	2	3	1	2	-	-	1	2	1	2	1	2
	Headache	2	3	1	2	1	2	-	-	2	3	-	-
	Presyncope	1	2	1	2	-	-	-	-	1	2	-	-
	Syncope	1	2	-	-	-	-	1	2	-	-	1	2
Psychiatric disorders	Any PT	2	3	1	2	1	2	-	-	2	3	1	2
	Anxiety	1	2	1	2	-	-	-	-	-	-	1	2
	Attention deficit hyperactivity disorder	1	2	-	-	1	2	-	-	1	2	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
	Insomnia	1	2	1	2	-	-	-	-	1	2	-	-
Reproductive system and breast disorders	Any PT	4	7	4	7	-	-	-	-	3	5	1	2
	Breast pain	1	2	1	2	-	-	-	-	1	2	-	-
	Vaginal haemorrhage	1	2	1	2	-	-	-	-	-	-	1	2
	Vulvovaginal pruritus	2	3	2	3	-	-	-	-	2	3	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	8	13	8	13	1	2	-	-	7	12	3	5
	Diaphragmatic spasm	1	2	1	2	-	-	-	-	-	-	1	2
	Dyspnoea exertional	1	2	1	2	-	-	-	-	1	2	-	-
	Nasal congestion	2	3	2	3	1	2	-	-	2	3	1	2
	Oropharyngeal pain	4	7	4	7	-	-	-	-	4	7	1	2
	Upper-airway cough syndrome	1	2	1	2	-	-	-	-	1	2	1	2
Skin and subcutaneous tissue disorders	Any PT	7	12	5	8	2	3	-	-	3	5	4	7
	Dermatitis contact	1	2	1	2	-	-	-	-	1	2	-	-
	Erythema	1	2	1	2	-	-	-	-	1	2	-	-
	Hyperhidrosis	1	2	-	-	1	2	-	-	-	-	1	2
	Night sweats	1	2	-	-	1	2	-	-	-	-	1	2
	Petechiae	1	2	1	2	-	-	-	-	-	-	1	2
	Rash	1	2	1	2	-	-	-	-	1	2	-	-
	Urticaria	1	2	1	2	-	-	-	-	-	-	1	2
Vascular disorders	Any PT	4	7	4	7	-	-	-	-	3	5	1	2
	Hypertension	1	2	1	2	-	-	-	-	1	2	-	-
	Hypotension	1	2	1	2	-	-	-	-	1	2	-	-
	Systolic hypertension	1	2	1	2	-	-	-	-	1	2	-	-
	Vasodilatation	1	2	1	2	-	-	-	-	-	-	1	2

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 118:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 56-70 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	7	70	6	60	4	40	-	-	5	50	2	20
General disorders and administration site conditions	Injection site bruising	2	20	2	20	-	-	-	-	2	20	-	-
Infections and infestations	Onychomycosis	1	10	-	-	1	10	-	-	1	10	-	-
Injury, poisoning and procedural complications	Any PT	2	20	-	-	2	20	-	-	2	20	-	-
	Exposure via inhalation	1	10	-	-	1	10	-	-	1	10	-	-
	Limb injury	1	10	-	-	1	10	-	-	1	10	-	-
Investigations	Bone density decreased	1	10	-	-	1	10	-	-	1	10	-	-
Metabolism and nutrition disorders	Decreased appetite	1	10	-	-	1	10	-	-	-	-	1	10
Musculoskeletal and connective tissue disorders	Pain in extremity	1	10	1	10	-	-	-	-	1	10	-	-
Nervous system disorders	Any PT	2	20	2	20	1	10	-	-	2	20	-	-
	Headache	1	10	1	10	-	-	-	-	1	10	-	-
	Sciatica	1	10	1	10	1	10	-	-	1	10	-	-
Psychiatric disorders	Insomnia	1	10	1	10	-	-	-	-	-	-	1	10
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	1	10	1	10	-	-	-	-	1	10	-	-

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 119:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 56-70 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	**Any PT**	7	70	4	40	3	30	1	10	6	60	1	10
Cardiac disorders	**Bradycardia**	2	20	2	20	-	-	-	-	2	20	-	-
Gastrointestinal disorders	**Abdominal discomfort**	1	10	-	-	1	10	-	-	-	-	1	10
Infections and infestations	**Any PT**	2	20	-	-	1	10	1	10	2	20	-	-
	Urinary tract infection	1	10	-	-	1	10	-	-	1	10	-	-
	Viral infection	1	10	-	-	-	-	1	10	1	10	-	-
Injury, poisoning and procedural complications	**Any PT**	3	30	2	20	1	10	-	-	3	30	-	-
	Muscle strain	1	10	1	10	-	-	-	-	1	10	-	-
	Skin laceration	1	10	1	10	-	-	-	-	1	10	-	-
	Tooth fracture	1	10	-	-	1	10	-	-	1	10	-	-

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 120
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 56-70 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	8	80	5	50	2	20	1	10	8	80	1	10
Ear and labyrinth disorders	Vertigo	1	10	1	10	-	-	-	-	-	-	1	10
Gastrointestinal disorders	Haemorrhoids	1	10	1	10	-	-	-	-	1	10	-	-
Infections and infestations	Paronychia	1	10	-	-	1	10	-	-	1	10	-	-
Injury, poisoning and procedural complications	Arthropod sting	1	10	1	10	-	-	-	-	1	10	-	-
Metabolism and nutrition disorders	Hypoglycaemia	1	10	-	-	-	-	1	10	1	10	-	-
Nervous system disorders	Dizziness	1	10	1	10	-	-	-	-	1	10	-	-
Respiratory, thoracic and mediastinal disorders	Any PT	2	20	1	10	1	10	-	-	2	20	-	-
	Nasal congestion	1	10	-	-	1	10	-	-	1	10	-	-
	Oropharyngeal pain	1	10	1	10	-	-	-	-	1	10	-	-
Skin and subcutaneous tissue disorders	Any PT	1	10	-	-	1	10	-	-	1	10	-	-
	Dermatitis contact	1	10	-	-	1	10	-	-	1	10	-	-
	Rash maculo-papular	1	10	-	-	1	10	-	-	1	10	-	-
Vascular disorders	Systolic hypertension	1	10	1	10	-	-	-	-	1	10	-	-

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 121:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 56-70 years (N=30)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	22	73	15	50	9	30	2	7	19	63	4	13
Cardiac disorders	Bradycardia	2	7	2	7	-	-	-	-	2	7	-	-
Ear and labyrinth disorders	Vertigo	1	3	1	3	-	-	-	-	-	-	1	3
Gastrointestinal disorders	Any PT	2	7	1	3	1	3	-	-	1	3	1	3
	Abdominal discomfort	1	3	-	-	1	3	-	-	-	-	1	3
	Haemorrhoids	1	3	1	3	-	-	-	-	1	3	-	-
General disorders and administration site conditions	Injection site bruising	2	7	2	7	-	-	-	-	2	7	-	-
Infections and infestations	Any PT	4	13	-	-	3	10	1	3	4	13	-	-
	Onychomycosis	1	3	-	-	1	3	-	-	1	3	-	-
	Paronychia	1	3	-	-	1	3	-	-	1	3	-	-
	Urinary tract infection	1	3	-	-	1	3	-	-	1	3	-	-
	Viral infection	1	3	-	-	-	-	1	3	1	3	-	-
Injury, poisoning and procedural complications	Any PT	6	20	3	10	3	10	-	-	6	20	-	-
	Arthropod sting	1	3	1	3	-	-	-	-	1	3	-	-
	Exposure via inhalation	1	3	-	-	1	3	-	-	1	3	-	-
	Limb injury	1	3	-	-	1	3	-	-	1	3	-	-
	Muscle strain	1	3	1	3	-	-	-	-	1	3	-	-
	Skin laceration	1	3	1	3	-	-	-	-	1	3	-	-
	Tooth fracture	1	3	-	-	1	3	-	-	1	3	-	-
Investigations	Bone density decreased	1	3	-	-	1	3	-	-	1	3	-	-
	Any PT	2	7	-	-	1	3	1	3	1	3	1	3

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Metabolism and nutrition disorders	Decreased appetite	1	3	-	-	1	3	-	-	-	-	1	3
	Hypoglycaemia	1	3	-	-	-	-	1	3	1	3	-	-
Musculoskeletal and connective tissue disorders	Pain in extremity	1	3	1	3	-	-	-	-	1	3	-	-
Nervous system disorders	Any PT	3	10	3	10	1	3	-	-	3	10	-	-
	Dizziness	1	3	1	3	-	-	-	-	1	3	-	-
	Headache	1	3	1	3	-	-	-	-	1	3	-	-
	Sciatica	1	3	1	3	1	3	-	-	1	3	-	-
Psychiatric disorders	Insomnia	1	3	1	3	-	-	-	-	-	-	1	3
Respiratory, thoracic and mediastinal disorders	Any PT	3	10	2	7	1	3	-	-	3	10	-	-
	Nasal congestion	1	3	-	-	1	3	-	-	1	3	-	-
	Oropharyngeal pain	2	7	2	7	-	-	-	-	2	7	-	-
Skin and subcutaneous tissue disorders	Any PT	1	3	-	-	1	3	-	-	1	3	-	-
	Dermatitis contact	1	3	-	-	1	3	-	-	1	3	-	-
	Rash maculo-papular	1	3	-	-	1	3	-	-	1	3	-	-
Vascular disorders	Systolic hypertension	1	3	1	3	-	-	-	-	1	3	-	-

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 122:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events
MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 25 µg mRNA-1273 ≥71 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	9	90	9	90	2	20	-	-	7	70	4	40
Cardiac disorders	Bradycardia	1	10	1	10	-	-	-	-	1	10	-	-
General disorders and administration site conditions	Any PT	2	20	2	20	-	-	-	-	1	10	1	10
	Energy increased	1	10	1	10	-	-	-	-	-	-	1	10
	Fatigue	1	10	1	10	-	-	-	-	-	-	1	10
	Injection site bruising	1	10	1	10	-	-	-	-	1	10	-	-
	Injection site pruritus	1	10	1	10	-	-	-	-	-	-	1	10
Infections and infestations	Pustule	1	10	1	10	-	-	-	-	1	10	-	-
Injury, poisoning and procedural complications	Any PT	5	50	5	50	-	-	-	-	5	50	-	-
	Arthropod bite	1	10	1	10	-	-	-	-	1	10	-	-
	Limb injury	1	10	1	10	-	-	-	-	1	10	-	-
	Procedural pain	1	10	1	10	-	-	-	-	1	10	-	-
	Skin abrasion	3	30	3	30	-	-	-	-	3	30	-	-
	Sunburn	1	10	1	10	-	-	-	-	1	10	-	-
	Thermal burn	1	10	1	10	-	-	-	-	1	10	-	-
Musculoskeletal and connective tissue disorders	Any PT	4	40	2	20	2	20	-	-	4	40	-	-
	Arthritis	1	10	-	-	1	10	-	-	1	10	-	-
	Joint swelling	1	10	1	10	-	-	-	-	1	10	-	-
	Muscle tightness	1	10	1	10	-	-	-	-	1	10	-	-
	Musculoskeletal chest pain	1	10	-	-	1	10	-	-	1	10	-	-
Nervous system disorders	Any PT	2	20	2	20	-	-	-	-	1	10	2	20

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
	Dizziness	2	20	2	20	-	-	-	-	1	10	1	10
	Visual field defect	1	10	1	10	-	-	-	-	-	-	1	10
Psychiatric disorders	**Any PT**	2	20	2	20	-	-	-	-	-	-	2	20
	Anxiety	1	10	1	10	-	-	-	-	-	-	1	10
	Sleep disorder	1	10	1	10	-	-	-	-	-	-	1	10
Skin and subcutaneous tissue disorders	**Any PT**	3	30	3	30	-	-	-	-	1	10	2	20
	Night sweats	1	10	1	10	-	-	-	-	-	-	1	10
	Pruritus	1	10	1	10	-	-	-	-	-	-	1	10
	Skin irritation	1	10	1	10	-	-	-	-	1	10	-	-

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 123:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 50 µg mRNA-1273 ≥71 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	**Any PT**	6	60	6	60	-	-	-	-	6	60	-	-
General disorders and administration site conditions	**Injection site bruising**	1	10	1	10	-	-	-	-	1	10	-	-
Injury, poisoning and procedural complications	**Any PT**	2	20	2	20	-	-	-	-	2	20	-	-
	Arthropod bite	1	10	1	10	-	-	-	-	1	10	-	-
	Injury	2	20	2	20	-	-	-	-	2	20	-	-
Respiratory, thoracic and mediastinal disorders	**Oropharyngeal pain**	1	10	1	10	-	-	-	-	1	10	-	-
Vascular disorders	**Hypertension**	2	20	2	20	-	-	-	-	2	20	-	-

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 124:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – 100 µg mRNA-1273 ≥71 years (N=10)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	8	80	8	80	-	-	-	-	7	70	3	30
Cardiac disorders	Bradycardia	1	10	1	10	-	-	-	-	1	10	-	-
General disorders and administration site conditions	Any PT	4	40	4	40	-	-	-	-	3	30	1	10
	Injection site bruising	1	10	1	10	-	-	-	-	1	10	-	-
	Injection site erythema	1	10	1	10	-	-	-	-	-	-	1	10
	Vessel puncture site bruise	3	30	3	30	-	-	-	-	3	30	-	-
Infections and infestations	Urinary tract infection	1	10	1	10	-	-	-	-	1	10	-	-
Injury, poisoning and procedural complications	Any PT	4	40	4	40	-	-	-	-	4	40	-	-
	Contusion	2	20	2	20	-	-	-	-	2	20	-	-
	Skin abrasion	3	30	3	30	-	-	-	-	3	30	-	-
	Tooth fracture	1	10	1	10	-	-	-	-	1	10	-	-
Musculoskeletal and connective tissue disorders	Myalgia	1	10	1	10	-	-	-	-	1	10	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	1	10	1	10	-	-	-	-	1	10	-	-
Nervous system disorders	Dizziness	1	10	1	10	-	-	-	-	-	-	1	10
Skin and subcutaneous tissue disorders	Any PT	4	40	4	40	-	-	-	-	3	30	1	10
	Blister	1	10	1	10	-	-	-	-	1	10	-	-
	Dermatitis	1	10	1	10	-	-	-	-	1	10	-	-
	Dermatitis contact	1	10	1	10	-	-	-	-	1	10	-	-
	Night sweats	1	10	1	10	-	-	-	-	-	-	1	10

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Rash	1	10	1	10	-	-	-	-	1	10	-	-
Vascular disorders	**Systolic hypertension**	1	10	1	10	-	-	-	-	1	10	-	-
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 125:
Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group – ≥71 years (N=30)

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	23	77	23	77	2	7	-	-	20	67	7	23
Cardiac disorders	Bradycardia	2	7	2	7	-	-	-	-	2	7	-	-
General disorders and administration site conditions	Any PT	7	23	7	23	-	-	-	-	5	17	2	7
	Energy increased	1	3	1	3	-	-	-	-	-	-	1	3
	Fatigue	1	3	1	3	-	-	-	-	-	-	1	3
	Injection site bruising	3	10	3	10	-	-	-	-	3	10	-	-
	Injection site erythema	1	3	1	3	-	-	-	-	-	-	1	3
	Injection site pruritus	1	3	1	3	-	-	-	-	-	-	1	3
	Vessel puncture site bruise	3	10	3	10	-	-	-	-	3	10	-	-
Infections and infestations	Any PT	2	7	2	7	-	-	-	-	2	7	-	-
	Pustule	1	3	1	3	-	-	-	-	1	3	-	-
	Urinary tract infection	1	3	1	3	-	-	-	-	1	3	-	-
Injury, poisoning and procedural complications	Any PT	11	37	11	37	-	-	-	-	11	37	-	-
	Arthropod bite	2	7	2	7	-	-	-	-	2	7	-	-
	Contusion	2	7	2	7	-	-	-	-	2	7	-	-
	Injury	2	7	2	7	-	-	-	-	2	7	-	-
	Limb injury	1	3	1	3	-	-	-	-	1	3	-	-
	Procedural pain	1	3	1	3	-	-	-	-	1	3	-	-
	Skin abrasion	6	20	6	20	-	-	-	-	6	20	-	-
	Sunburn	1	3	1	3	-	-	-	-	1	3	-	-
	Thermal burn	1	3	1	3	-	-	-	-	1	3	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
	Tooth fracture	1	3	1	3	-	-	-	-	1	3	-	-
Musculoskeletal and connective tissue disorders	Any PT	5	17	3	10	2	7	-	-	5	17	-	-
	Arthritis	1	3	-	-	1	3	-	-	1	3	-	-
	Joint swelling	1	3	1	3	-	-	-	-	1	3	-	-
	Muscle tightness	1	3	1	3	-	-	-	-	1	3	-	-
	Musculoskeletal chest pain	1	3	-	-	1	3	-	-	1	3	-	-
	Myalgia	1	3	1	3	-	-	-	-	1	3	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	1	3	1	3	-	-	-	-	1	3	-	-
Nervous system disorders	Any PT	3	10	3	10	-	-	-	-	1	3	3	10
	Dizziness	3	10	3	10	-	-	-	-	1	3	2	7
	Visual field defect	1	3	1	3	-	-	-	-	-	-	1	3
Psychiatric disorders	Any PT	2	7	2	7	-	-	-	-	-	-	2	7
	Anxiety	1	3	1	3	-	-	-	-	-	-	1	3
	Sleep disorder	1	3	1	3	-	-	-	-	-	-	1	3
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	1	3	1	3	-	-	-	-	1	3	-	-
Skin and subcutaneous tissue disorders	Any PT	7	23	7	23	-	-	-	-	4	13	3	10
	Blister	1	3	1	3	-	-	-	-	1	3	-	-
	Dermatitis	1	3	1	3	-	-	-	-	1	3	-	-
	Dermatitis contact	1	3	1	3	-	-	-	-	1	3	-	-
	Night sweats	2	7	2	7	-	-	-	-	-	-	2	7
	Pruritus	1	3	1	3	-	-	-	-	-	-	1	3
	Rash	1	3	1	3	-	-	-	-	1	3	-	-
	Skin irritation	1	3	1	3	-	-	-	-	1	3	-	-

				Severity						Relationship to Study Vaccination			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Vascular disorders	**Any PT**	3	10	3	10	-	-	-	-	3	10	-	-
	Hypertension	2	7	2	7	-	-	-	-	2	7	-	-
	Systolic hypertension	1	3	1	3	-	-	-	-	1	3	-	-
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 66: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group - 18-55 Years of Age

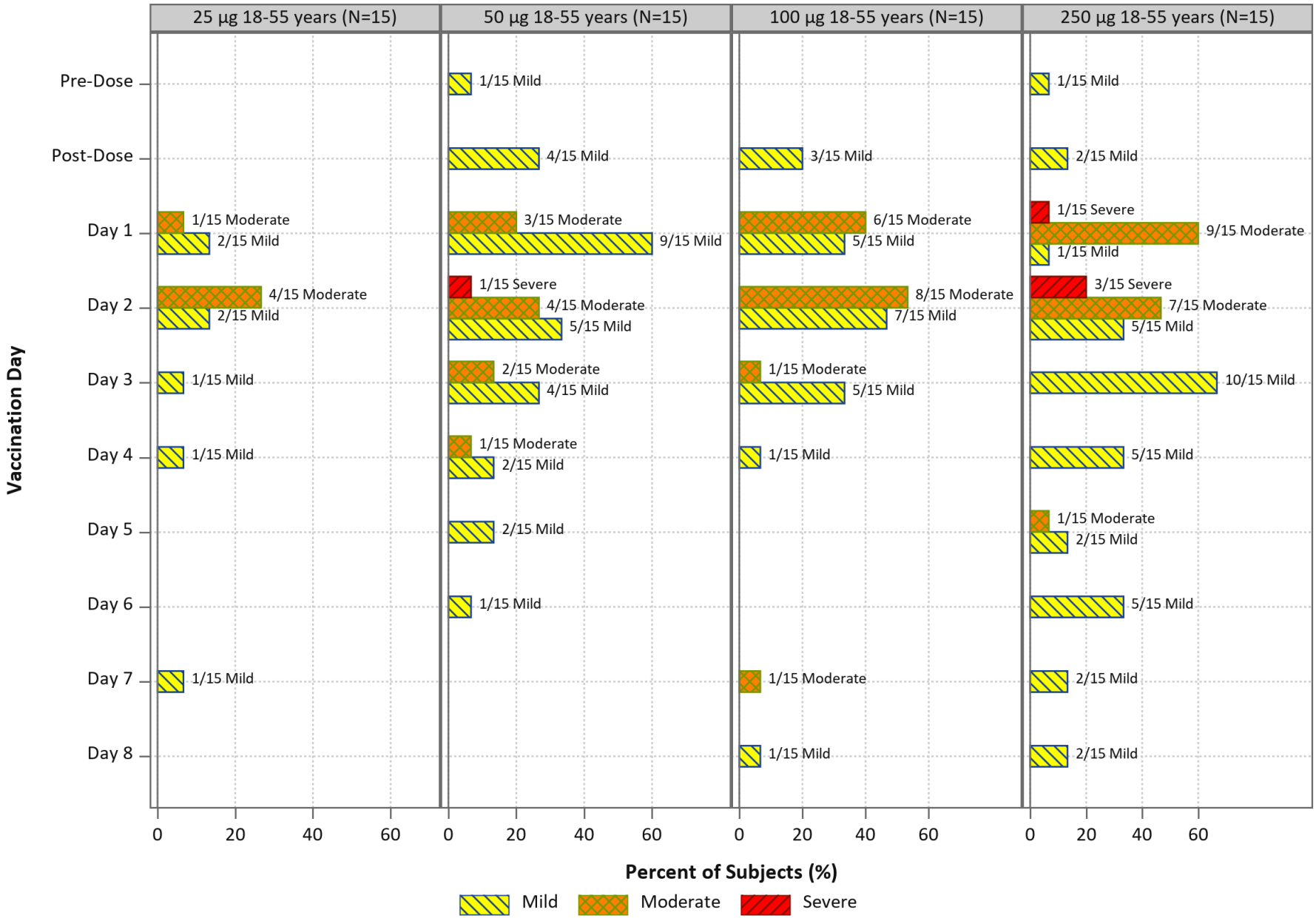

25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
1/15 Moderate
2/15 Mild
4/15 Moderate
2/15 Mild
1/15 Mild
1/15 Mild
1/15 Mild
4/15 Mild
3/15 Moderate
9/15 Mild
1/15 Severe
4/15 Moderate
5/15 Mild
2/15 Moderate
4/15 Mild
1/15 Moderate
2/15 Mild
2/15 Mild
1/15 Mild
1/15 Mild
3/15 Mild
6/15 Moderate
5/15 Mild
8/15 Moderate
7/15 Mild
1/15 Moderate
5/15 Mild
1/15 Mild
1/15 Moderate
1/15 Mild
1/15 Severe
9/15 Moderate
1/15 Mild
3/15 Severe
7/15 Moderate
5/15 Mild
10/15 Mild
5/15 Mild
1/15 Moderate
2/15 Mild
5/15 Mild
2/15 Mild
2/15 Mild
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 67: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group - 56-70 Years of Age

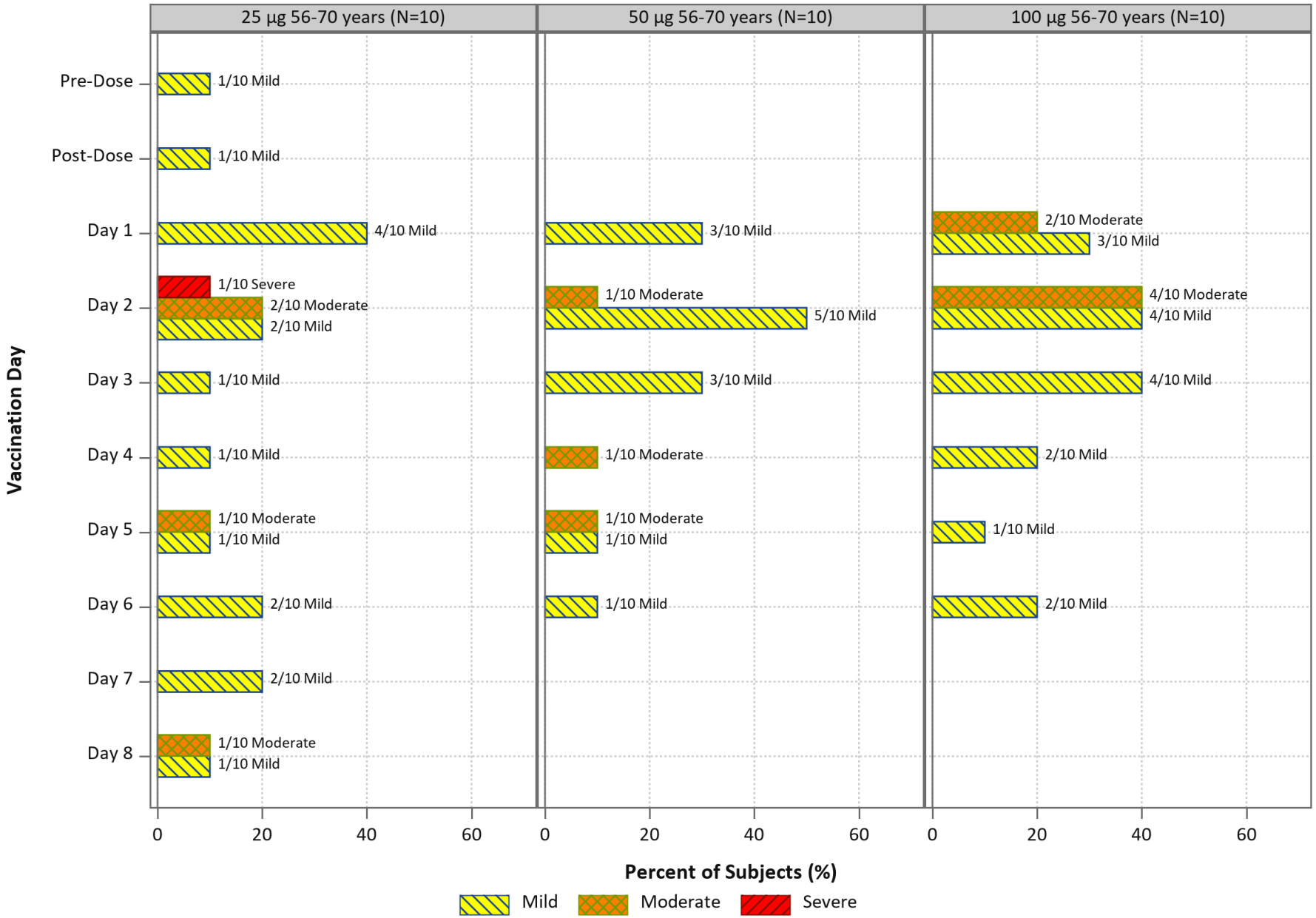

25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
1/10 Mild
1/10 Mild
4/10 Mild
1/10 Severe
2/10 Moderate
2/10 Mild
1/10 Mild
1/10 Mild
1/10 Moderate
1/10 Mild
2/10 Mild
2/10 Mild
1/10 Moderate
1/10 Mild
3/10 Mild
1/10 Moderate
5/10 Mild
3/10 Mild
1/10 Moderate
1/10 Moderate
1/10 Mild
1/10 Mild
2/10 Moderate
3/10 Mild
4/10 Moderate
4/10 Mild
4/10 Mild
2/10 Mild
1/10 Mild
2/10 Mild
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 68: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group - ≥71 years of Age

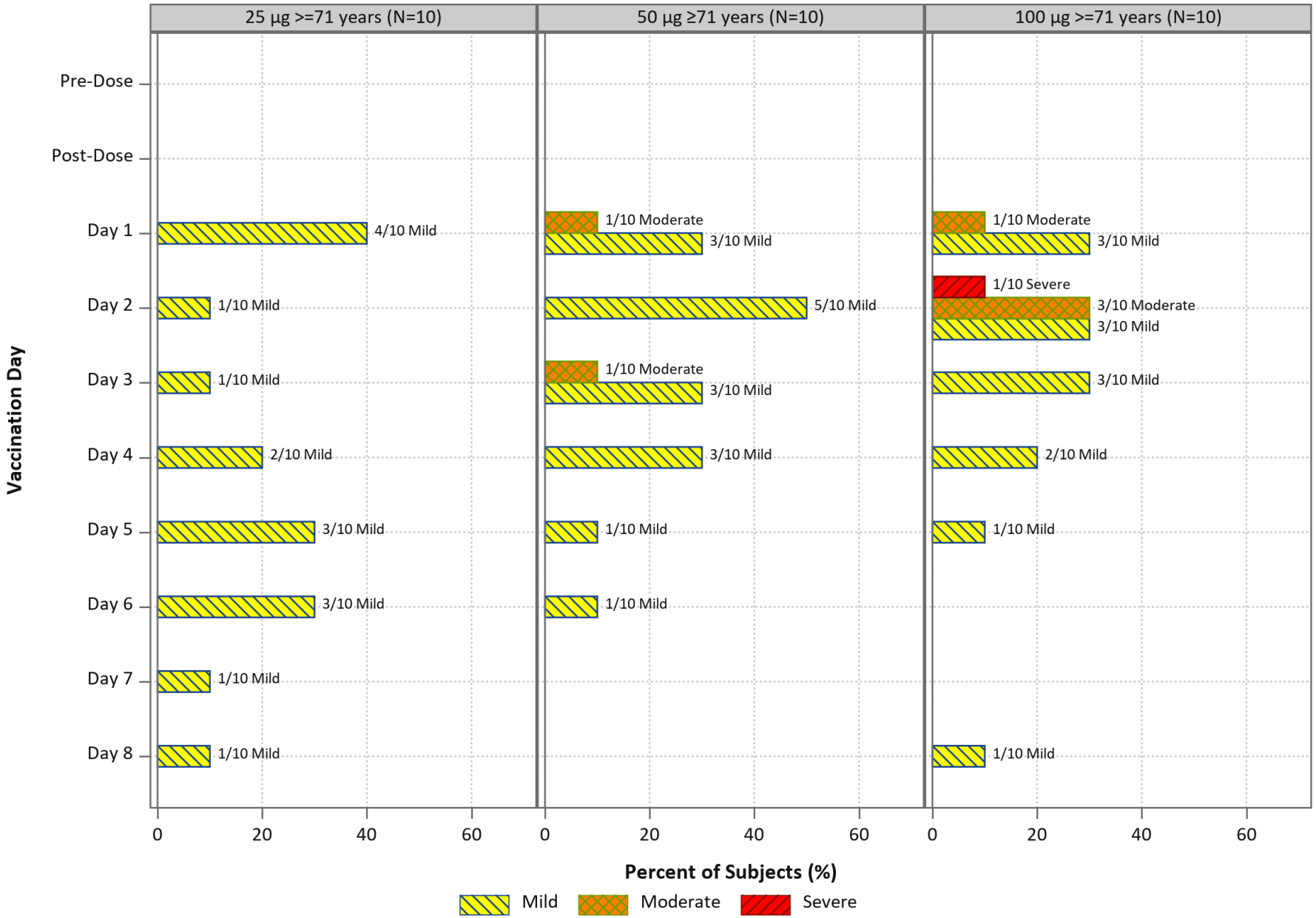

25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
4/10 Mild
1/10 Mild
1/10 Mild
2/10 Mild
3/10 Mild
3/10 Mild
1/10 Mild
1/10 Moderate
3/10 Mild
5/10 Mild
1/10 Moderate
3/10 Mild
3/10 Mild
1/10 Mild
1/10 Mild
1/10 Moderate
3/10 Mild
1/10 Severe
3/10 Moderate
3/10 Mild
3/10 Mild
2/10 Mild
1/10 Mild
1/10 Mild
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 69: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group - 18-55 Years of Age

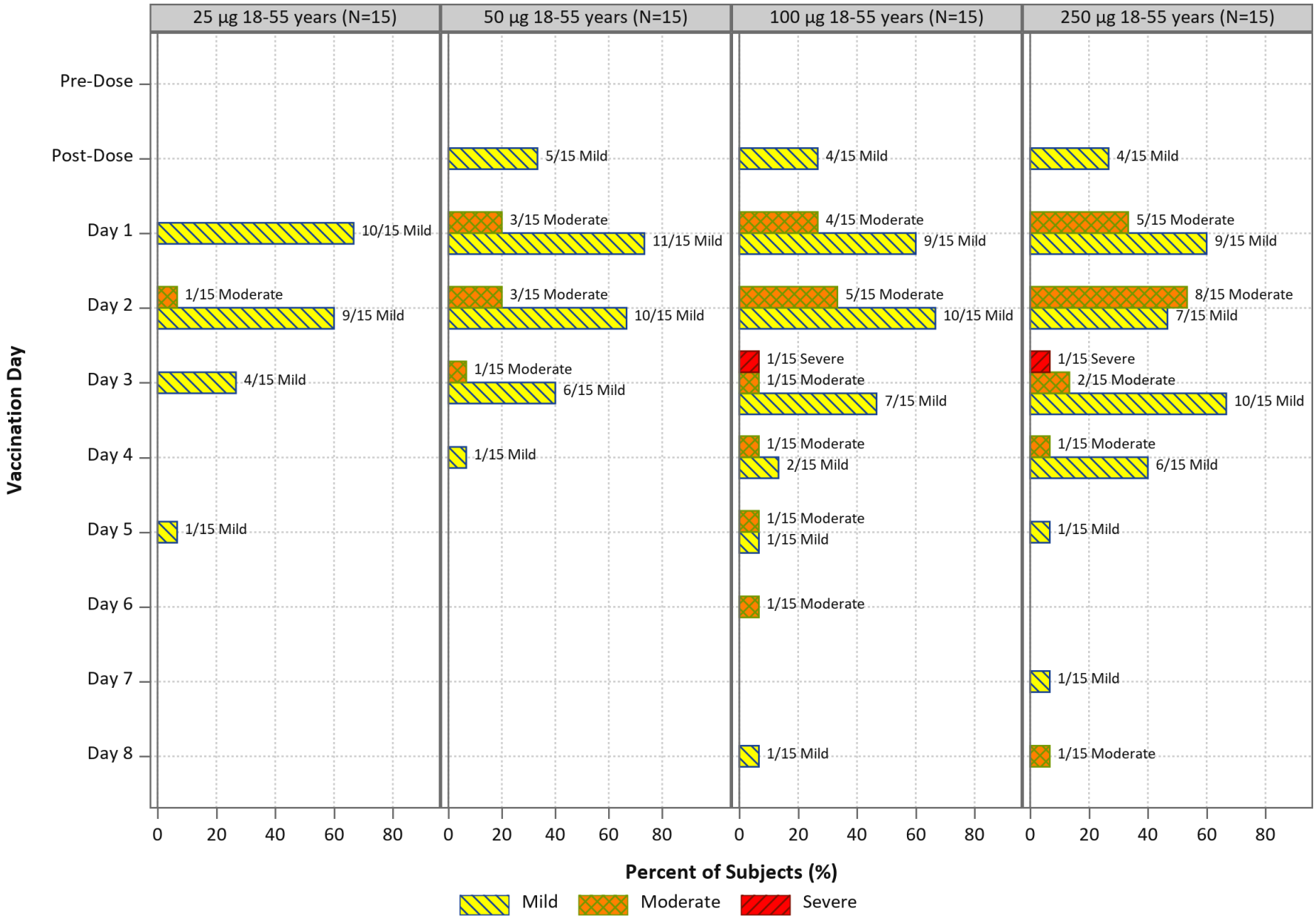

25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
10/15 Mild
1/15 Moderate
9/15 Mild
4/15 Mild
1/15 Mild
5/15 Mild
3/15 Moderate
11/15 Mild
3/15 Moderate
10/15 Mild
1/15 Moderate
6/15 Mild
1/15 Mild
4/15 Mild
4/15 Moderate
9/15 Mild
5/15 Moderate
10/15 Mild
1/15 Severe
1/15 Moderate
7/15 Mild
1/15 Moderate
2/15 Mild
1/15 Moderate
1/15 Mild
1/15 Moderate
1/15 Mild
4/15 Mild
5/15 Moderate
9/15 Mild
8/15 Moderate
7/15 Mild
1/15 Severe
2/15 Moderate
10/15 Mild
1/15 Moderate
6/15 Mild
1/15 Mild
1/15 Mild
1/15 Moderate
0
20
40
60
80
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 70: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group - 56-70 Years of Age

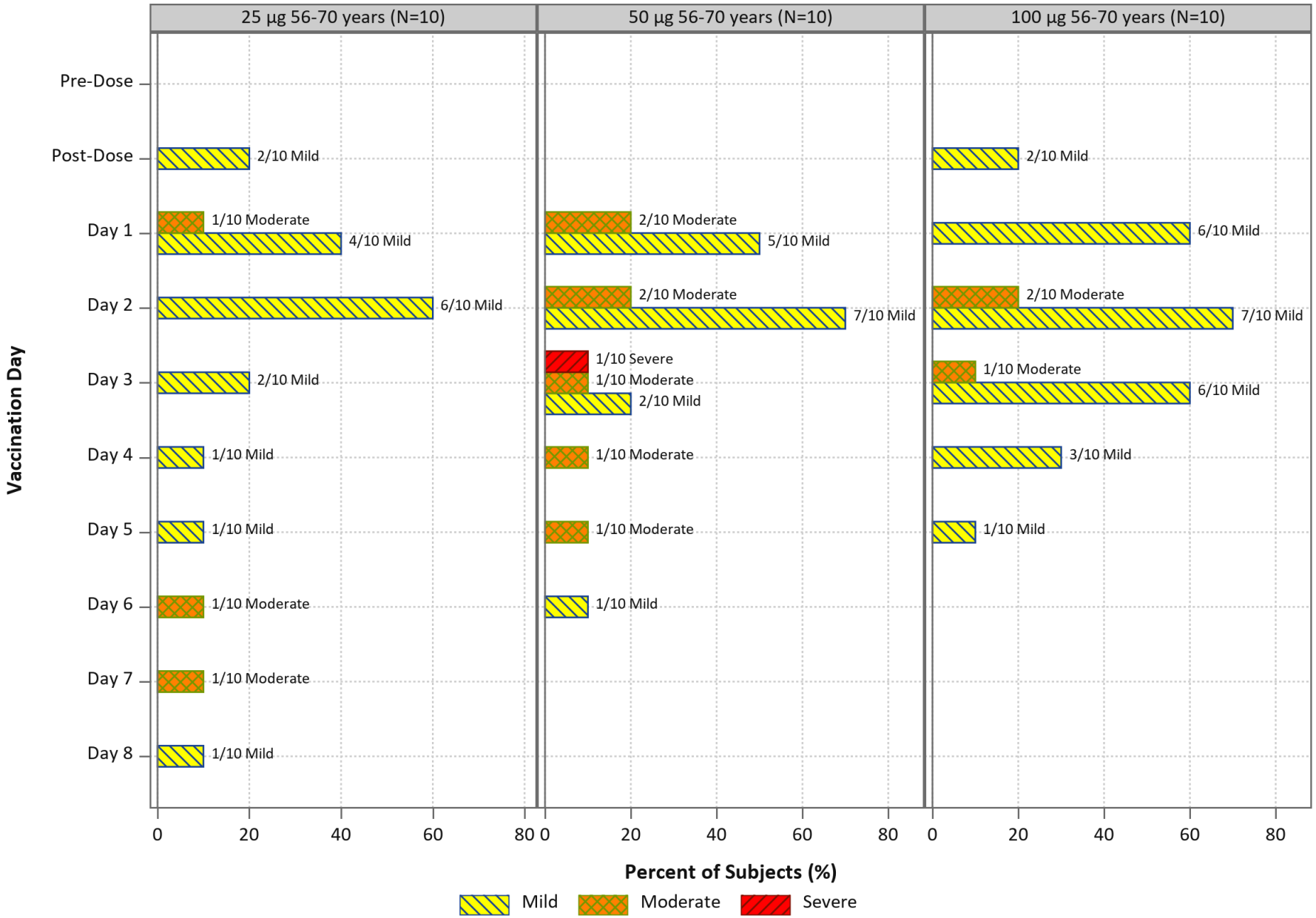

25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
2/10 Mild
1/10 Moderate
4/10 Mild
6/10 Mild
2/10 Mild
1/10 Mild
1/10 Mild
1/10 Moderate
1/10 Mild
2/10 Moderate
5/10 Mild
2/10 Moderate
7/10 Mild
1/10 Severe
1/10 Moderate
2/10 Mild
1/10 Moderate
1/10 Moderate
1/10 Mild
2/10 Mild
6/10 Mild
2/10 Moderate
7/10 Mild
1/10 Moderate
6/10 Mild
3/10 Mild
1/10 Mild
0
20
40
60
80
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 71: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group - ≥71 years of Age

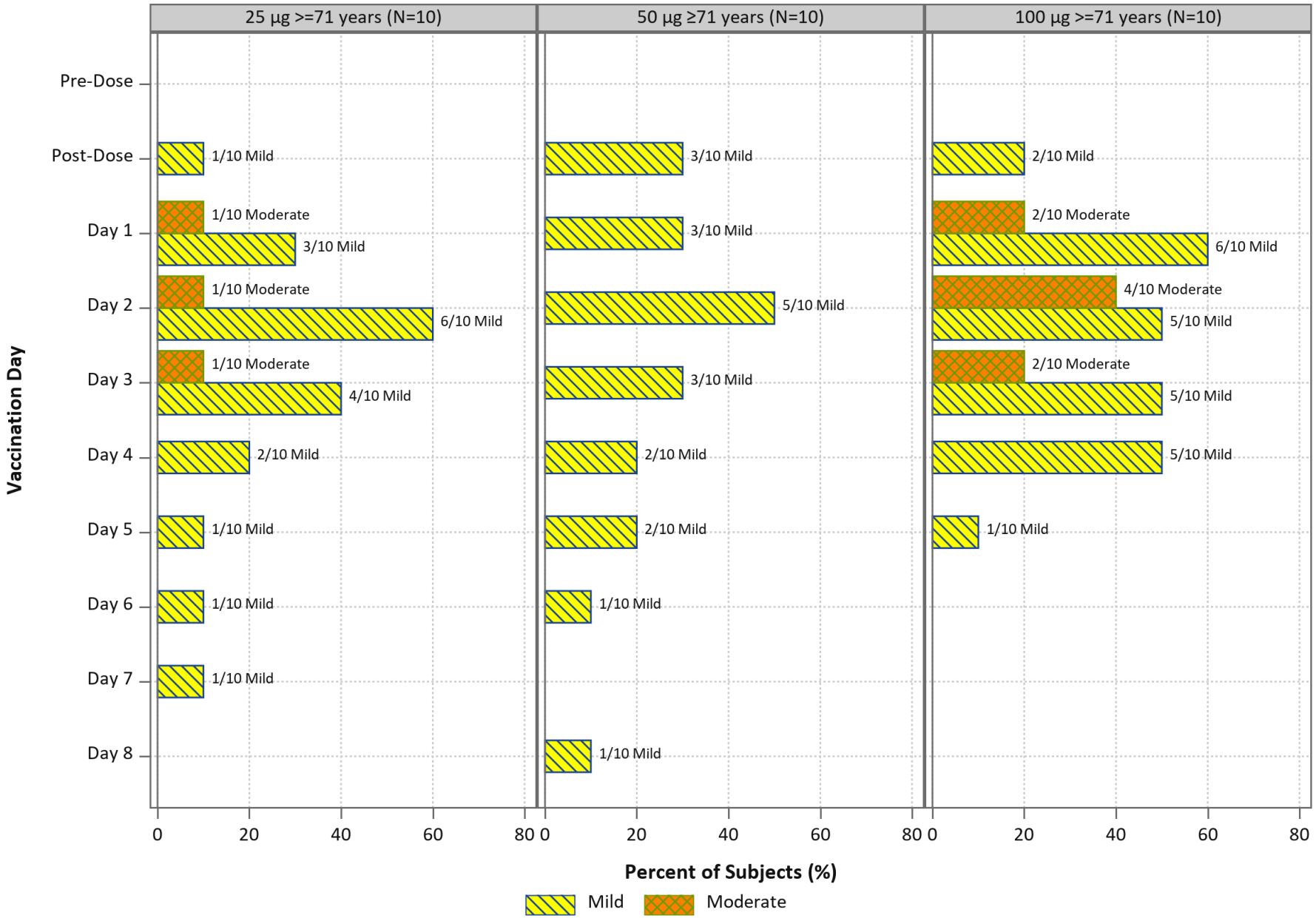

25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
1/10 Mild
1/10 Moderate
3/10 Mild
6/10 Mild
4/10 Mild
2/10 Mild
2/10 Moderate
4/10 Moderate
5/10 Mild
0
20
40
60
80
Percent of Subjects (%)
Mild
Moderate

Figure 72: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Dose 1

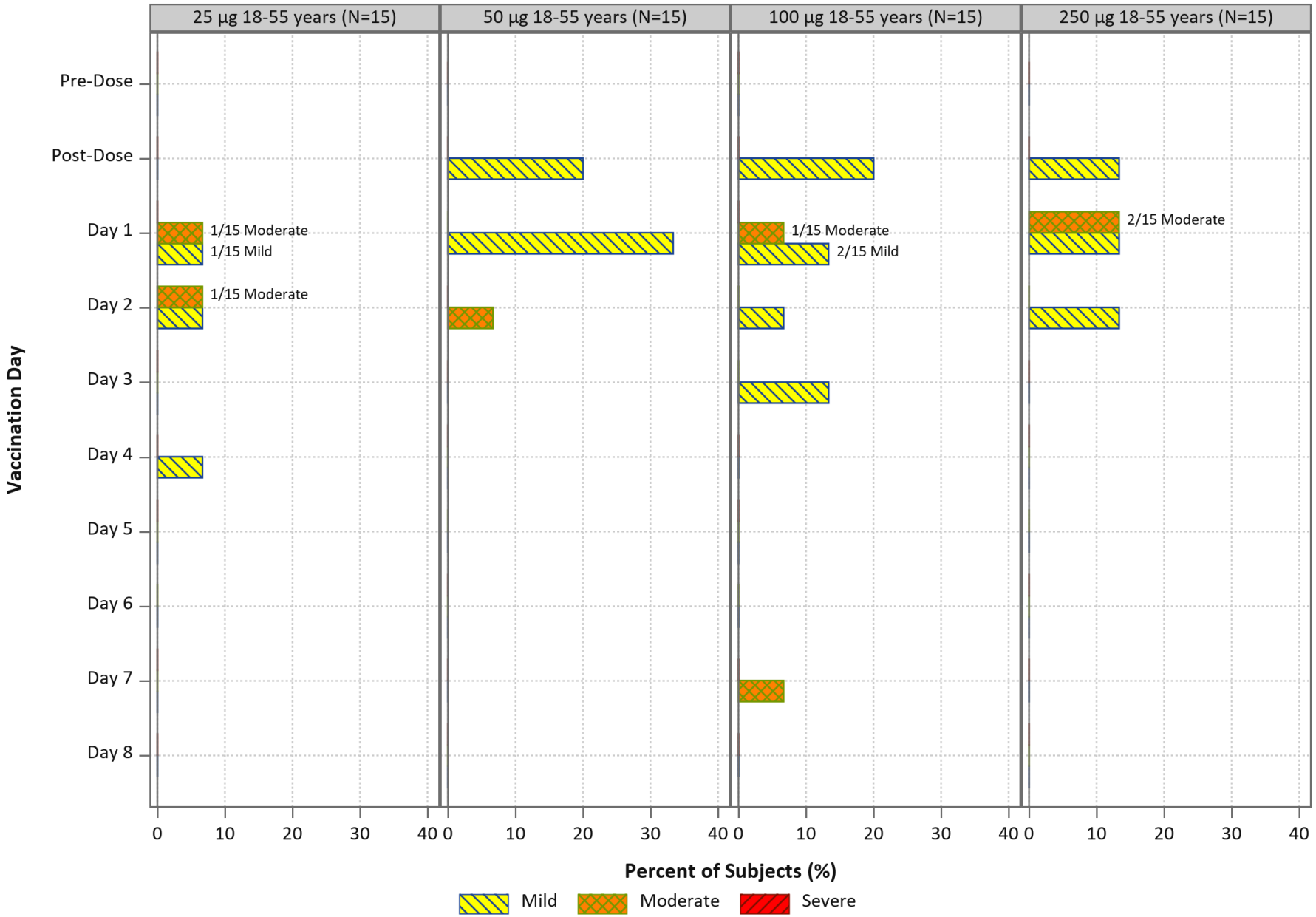

25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
1/15 Moderate
1/15 Mild
1/15 Moderate
1/15 Moderate
2/15 Mild
2/15 Moderate
0
10
20
30
40
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 73: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Dose 1

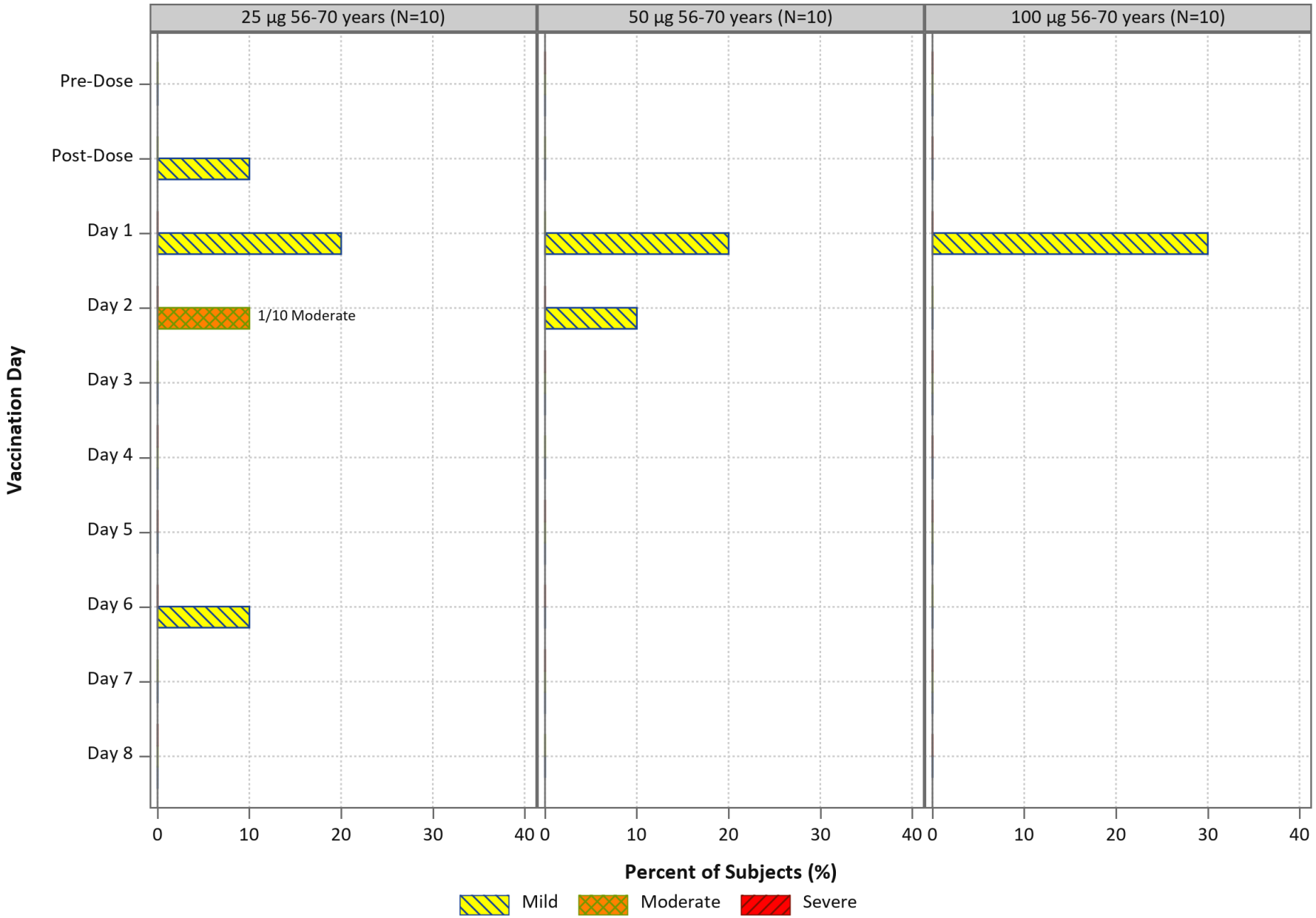

25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
1/10 Moderate
Vaccination Day
0
10
20
30
40
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 74: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group ≥71 years of Age - Dose 1

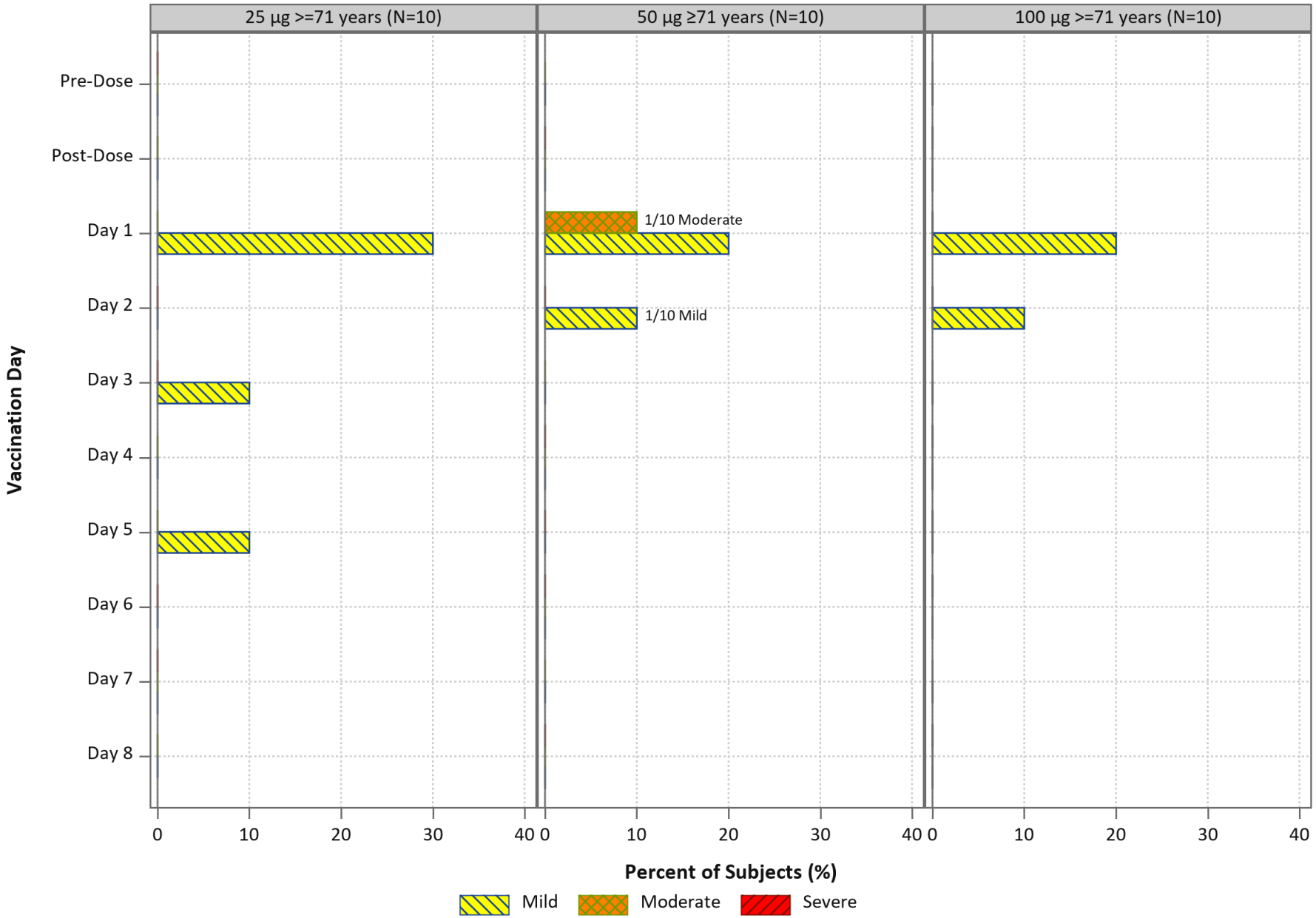

25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
1/10 Moderate
1/10 Mild
0
10
20
30
40
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 75: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Dose 1

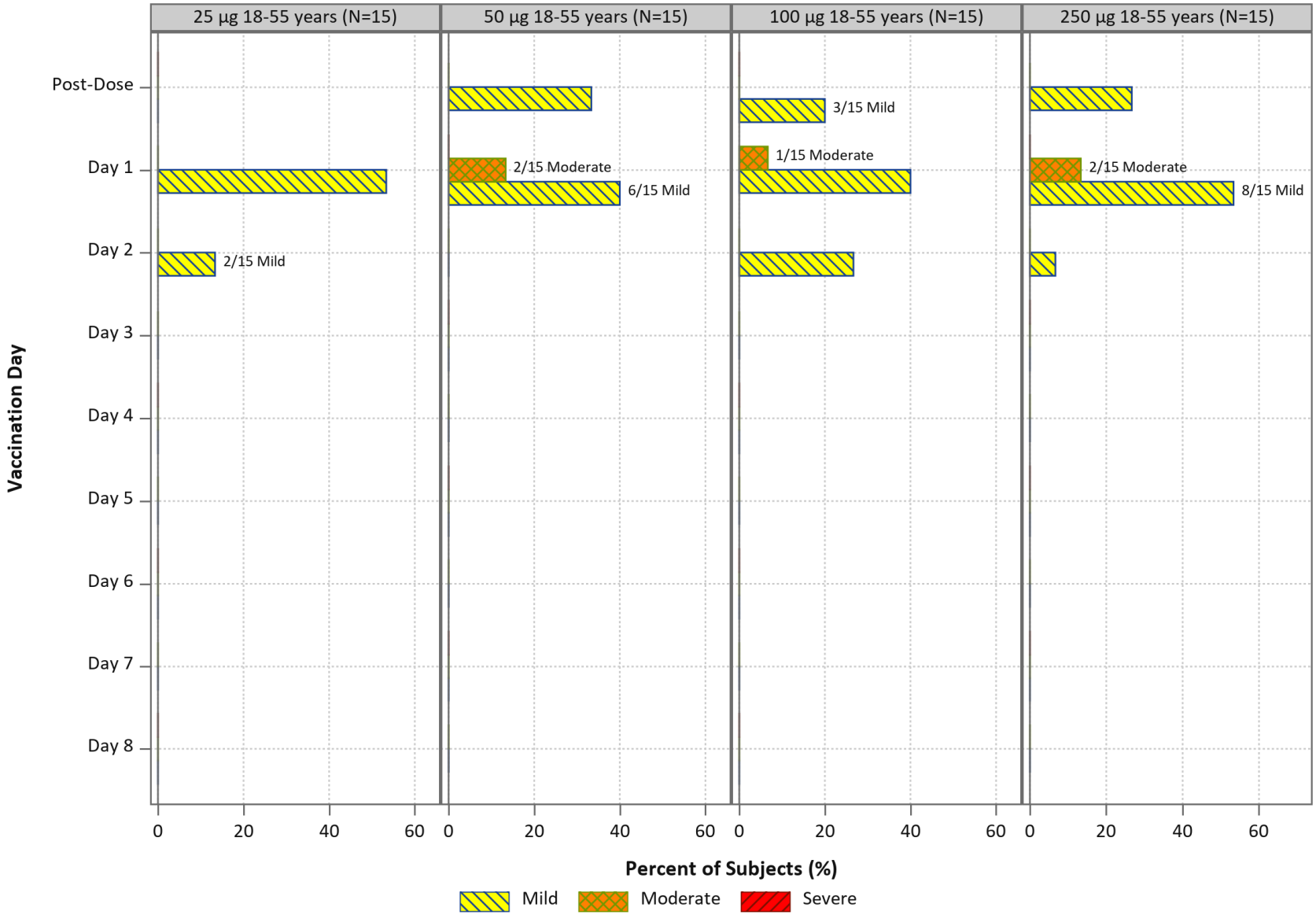


Figure 76: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Dose 1

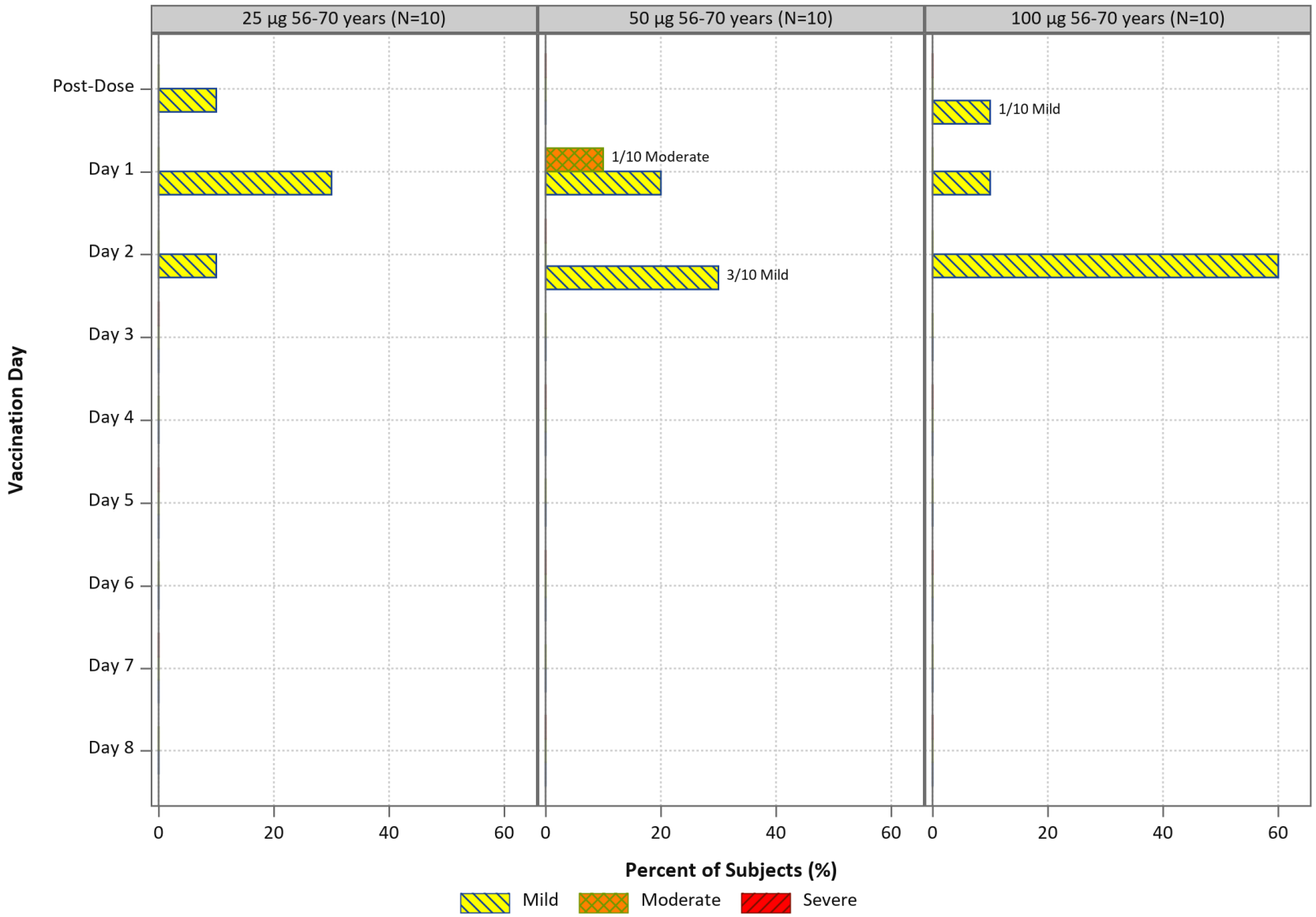


Figure 77: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group ≥71 years of Age - Dose 1

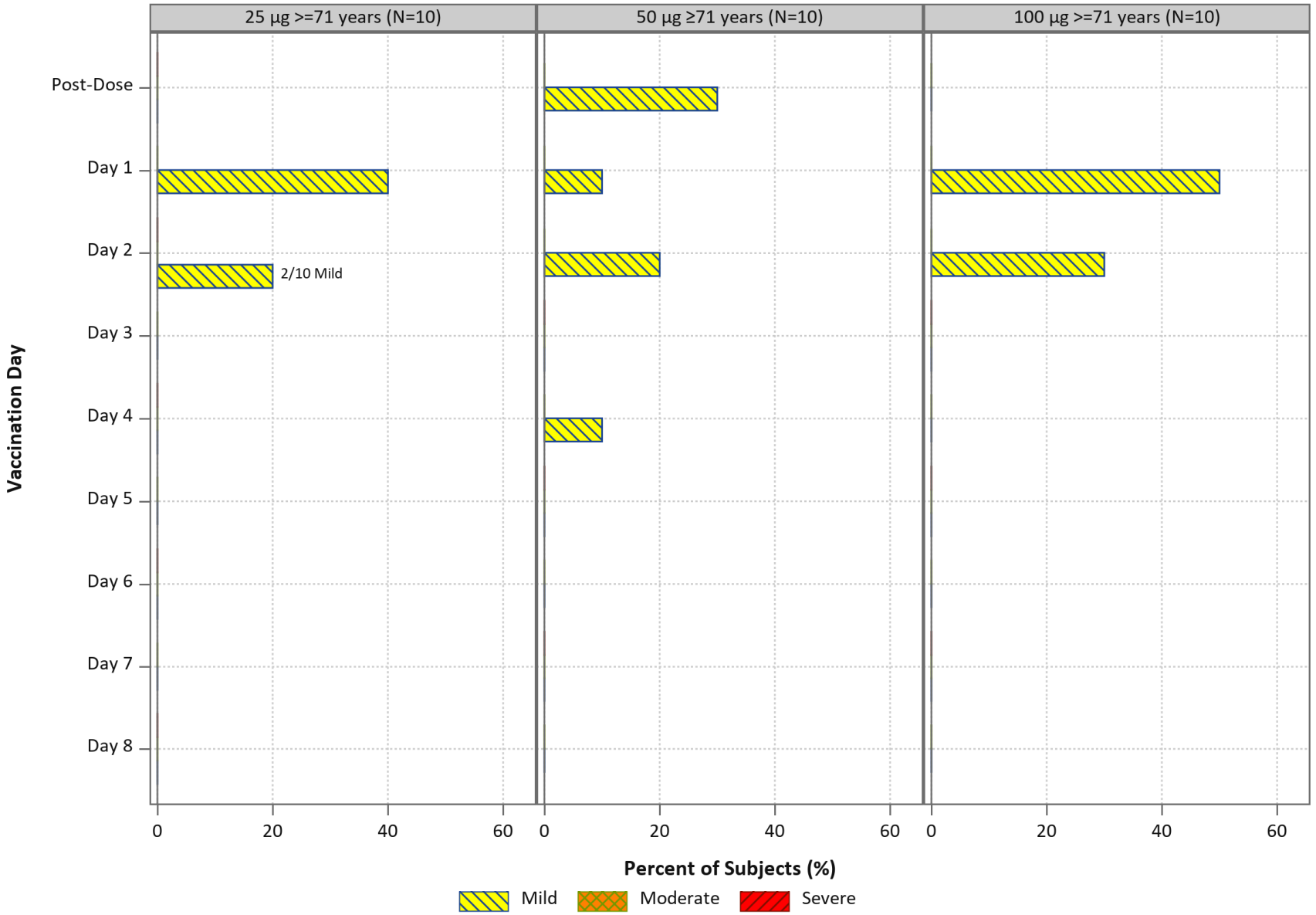


Figure 78: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Dose 2

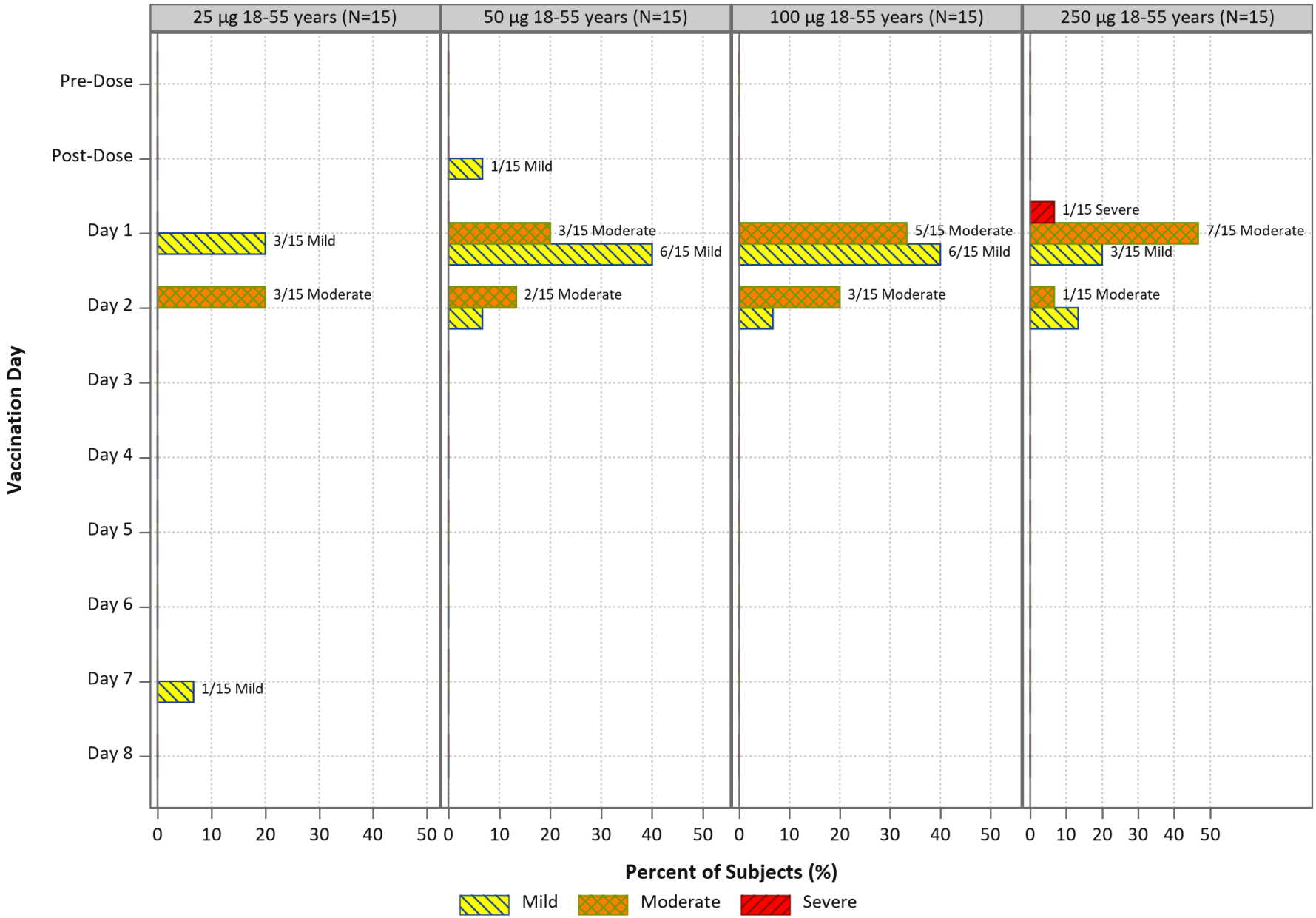

25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Vaccination Day
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
3/15 Mild
3/15 Moderate
1/15 Mild
1/15 Mild
3/15 Moderate
6/15 Mild
2/15 Moderate
5/15 Moderate
6/15 Mild
3/15 Moderate
1/15 Severe
7/15 Moderate
3/15 Mild
1/15 Moderate
0 10 20 30 40 50
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 79: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Dose 2

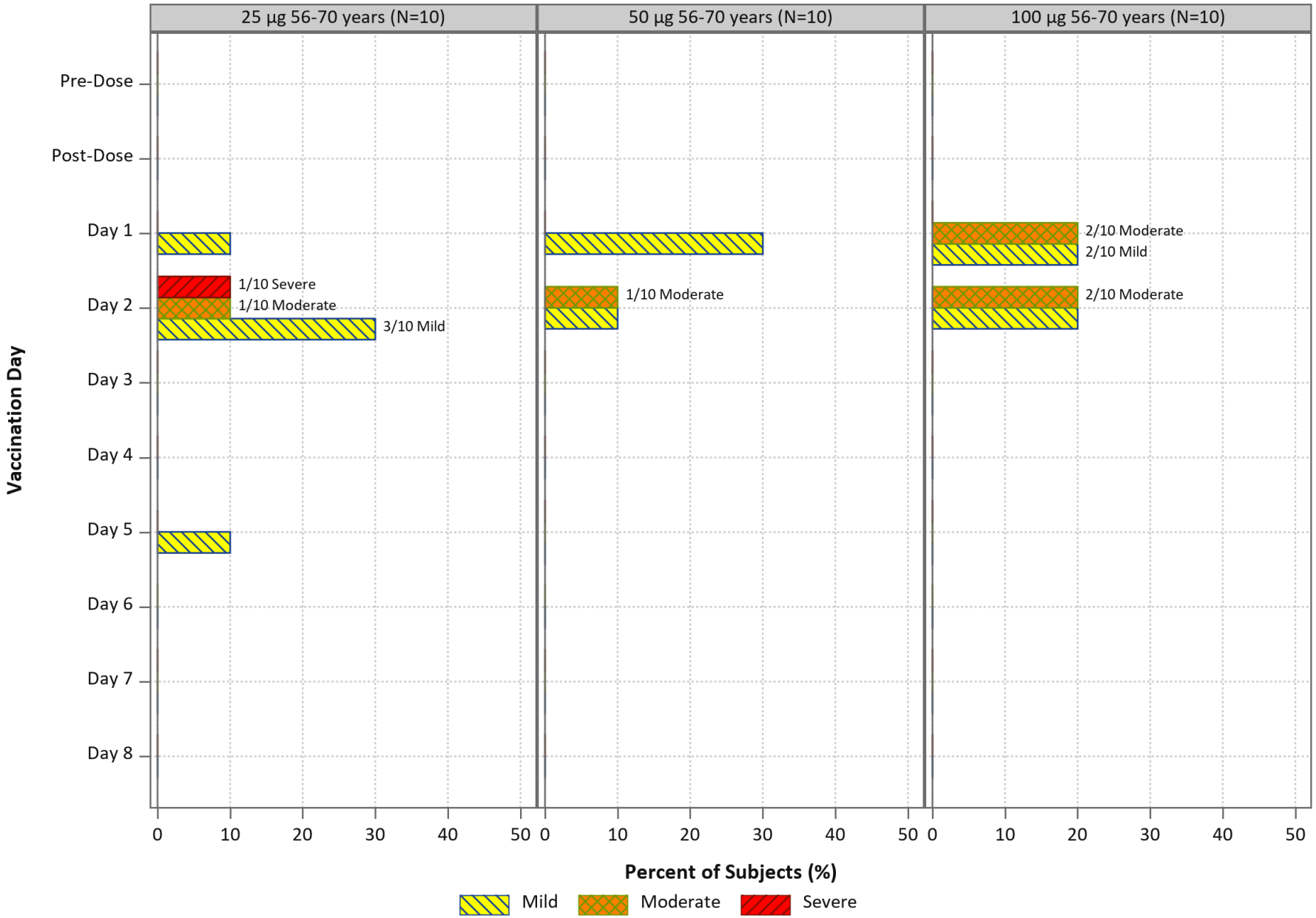

25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
1/10 Severe
1/10 Moderate
3/10 Mild
1/10 Moderate
2/10 Moderate
2/10 Mild
2/10 Moderate
0
10
20
30
40
50
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 80: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group ≥71 years of Age - Dose 2

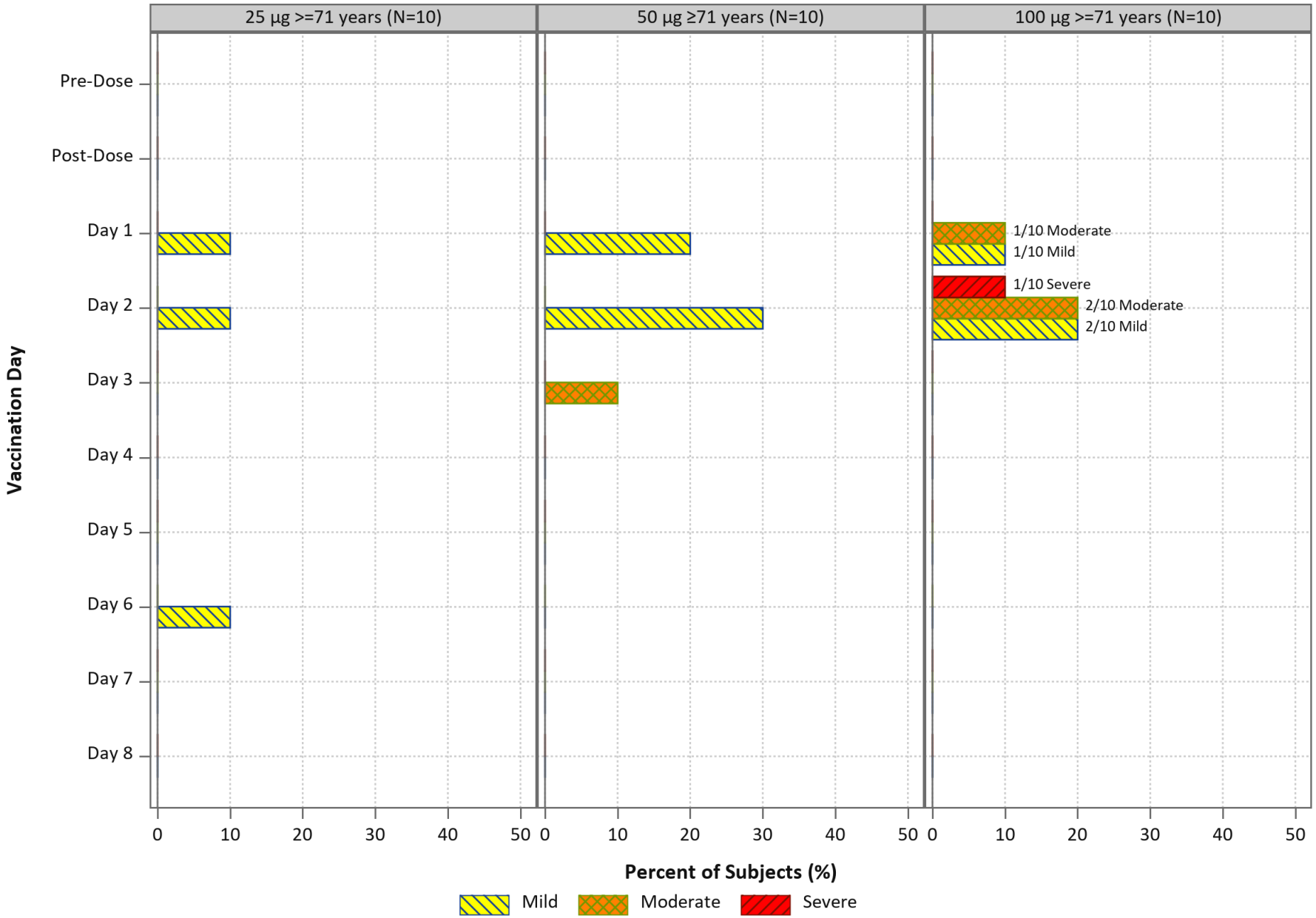

25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Pre-Dose
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
1/10 Moderate
1/10 Mild
1/10 Severe
2/10 Moderate
2/10 Mild
0
10
20
30
40
50
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 81: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Dose 2

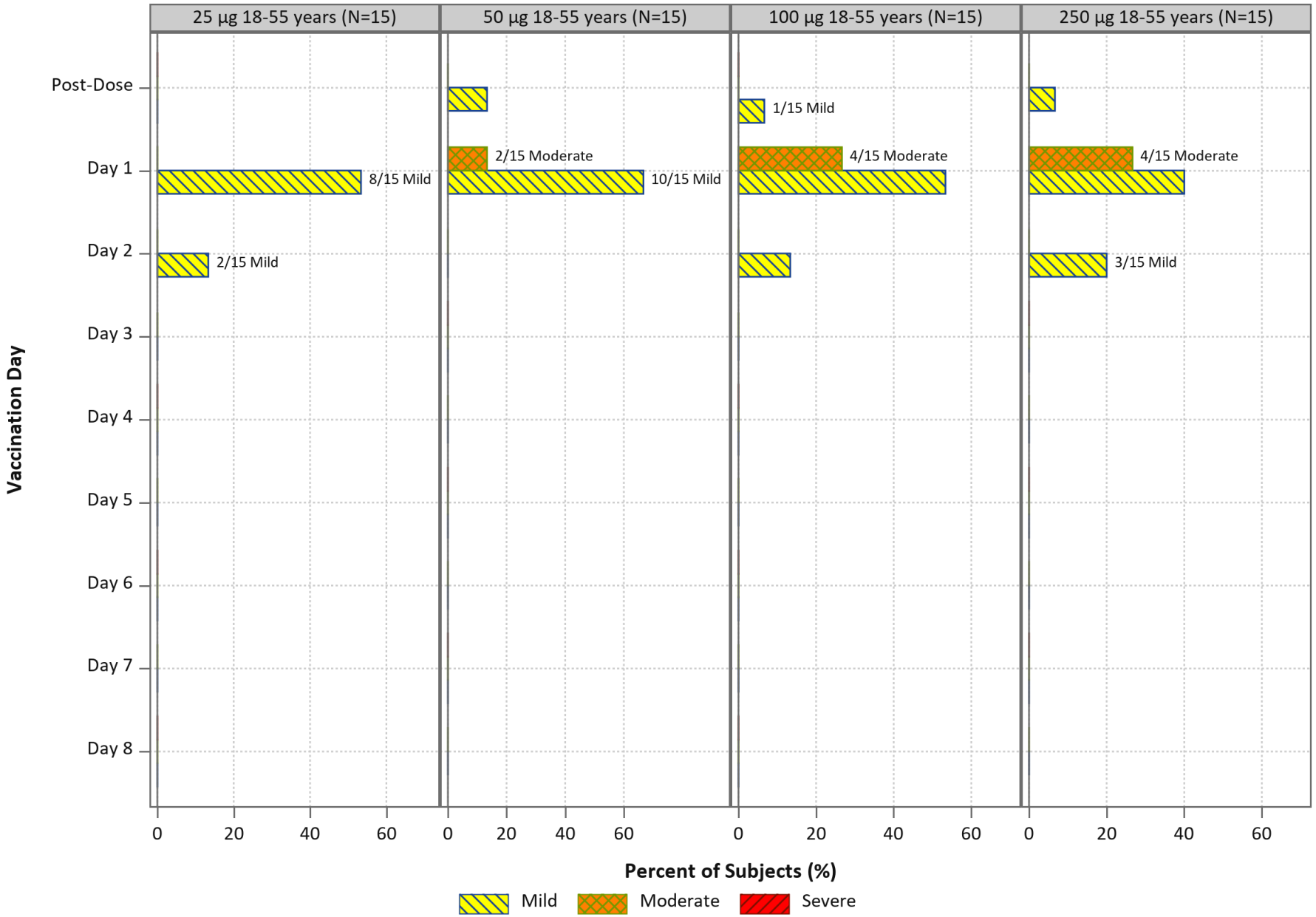

25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
8/15 Mild
2/15 Mild
2/15 Moderate
10/15 Mild
1/15 Mild
4/15 Moderate
4/15 Moderate
3/15 Mild
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 82: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Dose 2

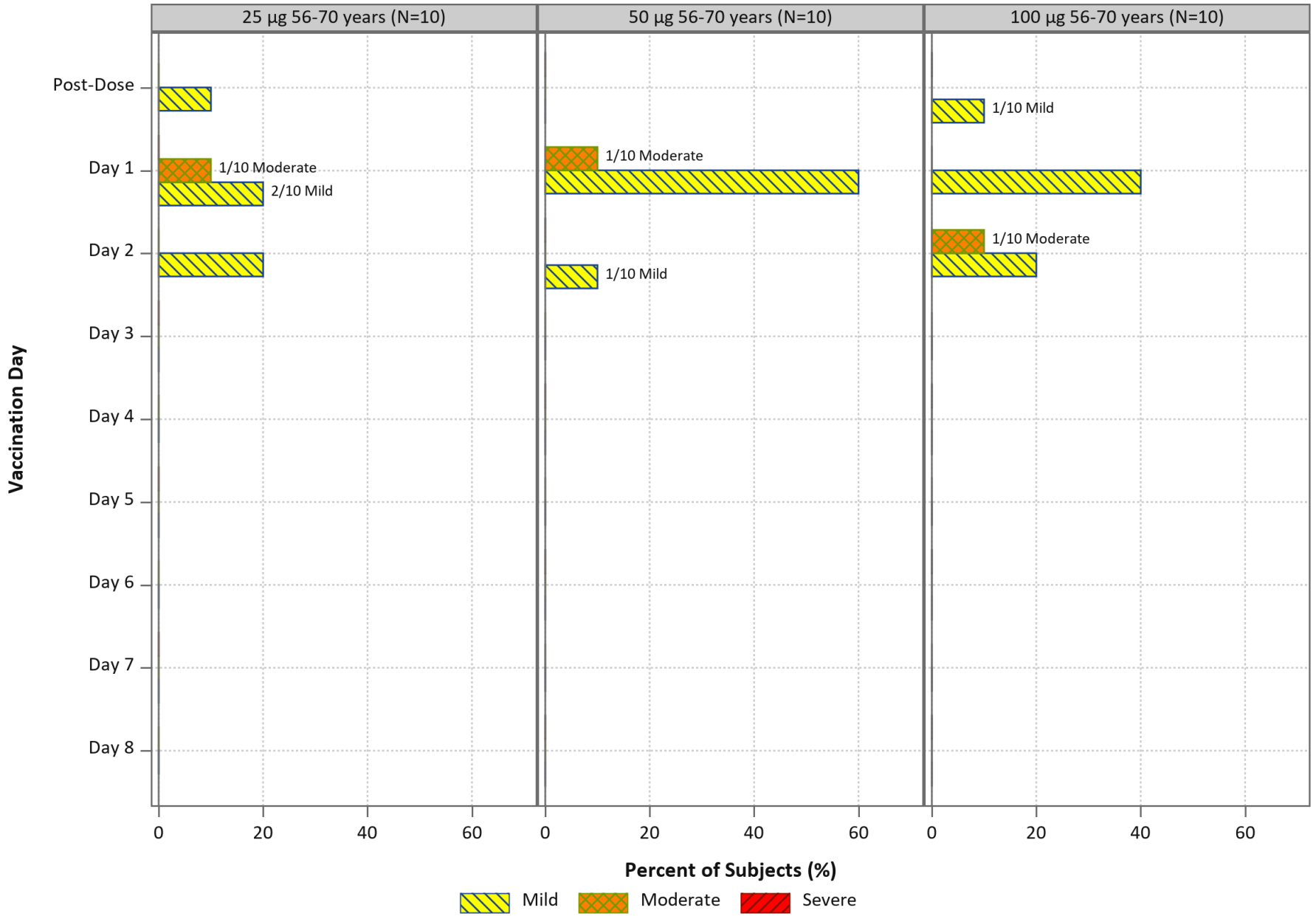

25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
1/10 Moderate
2/10 Mild
1/10 Moderate
1/10 Mild
1/10 Mild
1/10 Moderate
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 83: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group ≥71 years of Age - Dose 2

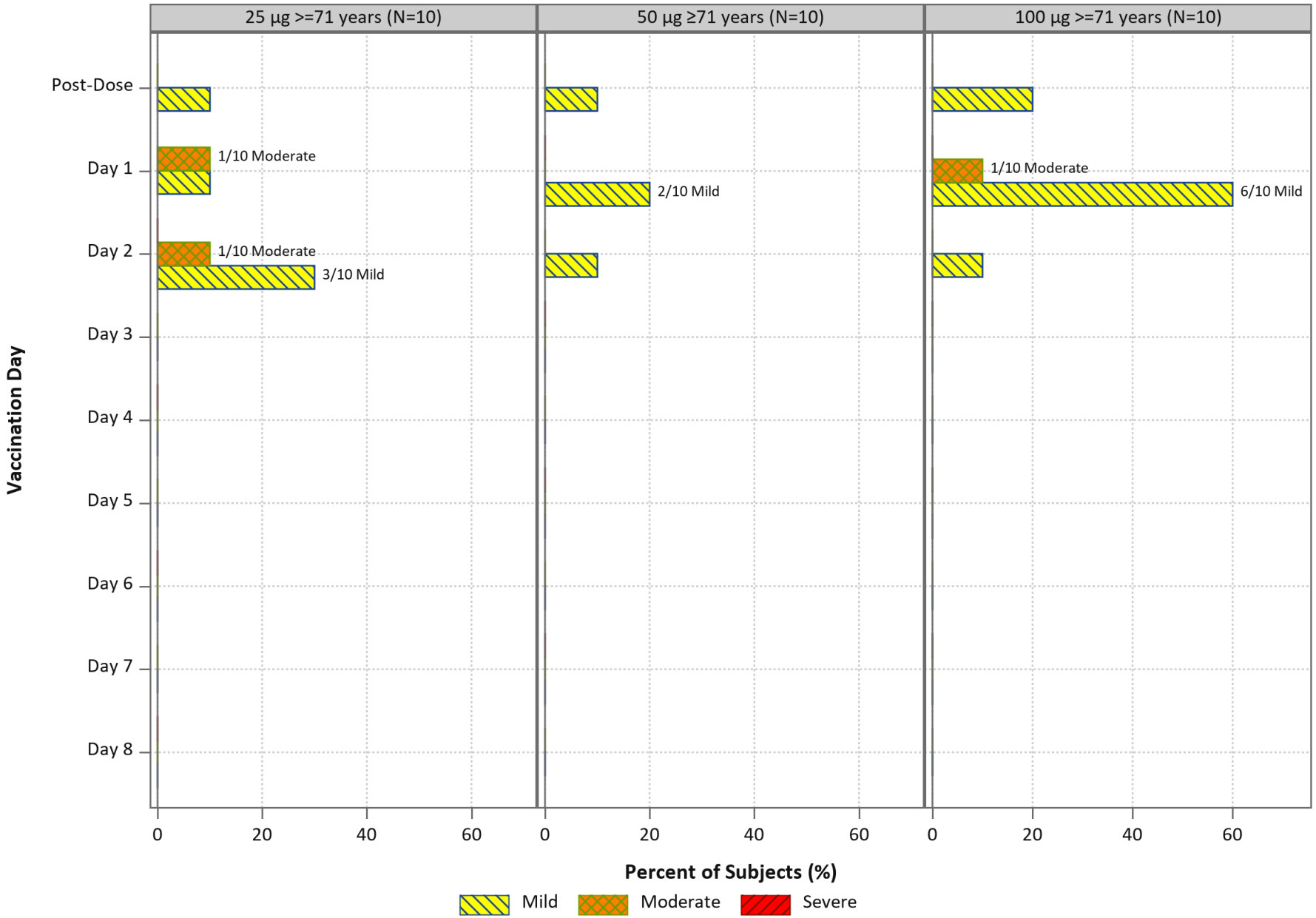

25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Post-Dose
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Vaccination Day
1/10 Moderate
1/10 Moderate
3/10 Mild
2/10 Mild
1/10 Moderate
6/10 Mild
0
20
40
60
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 84: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Arthralgia



Figure 85: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Arthralgia



Figure 86: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Arthralgia

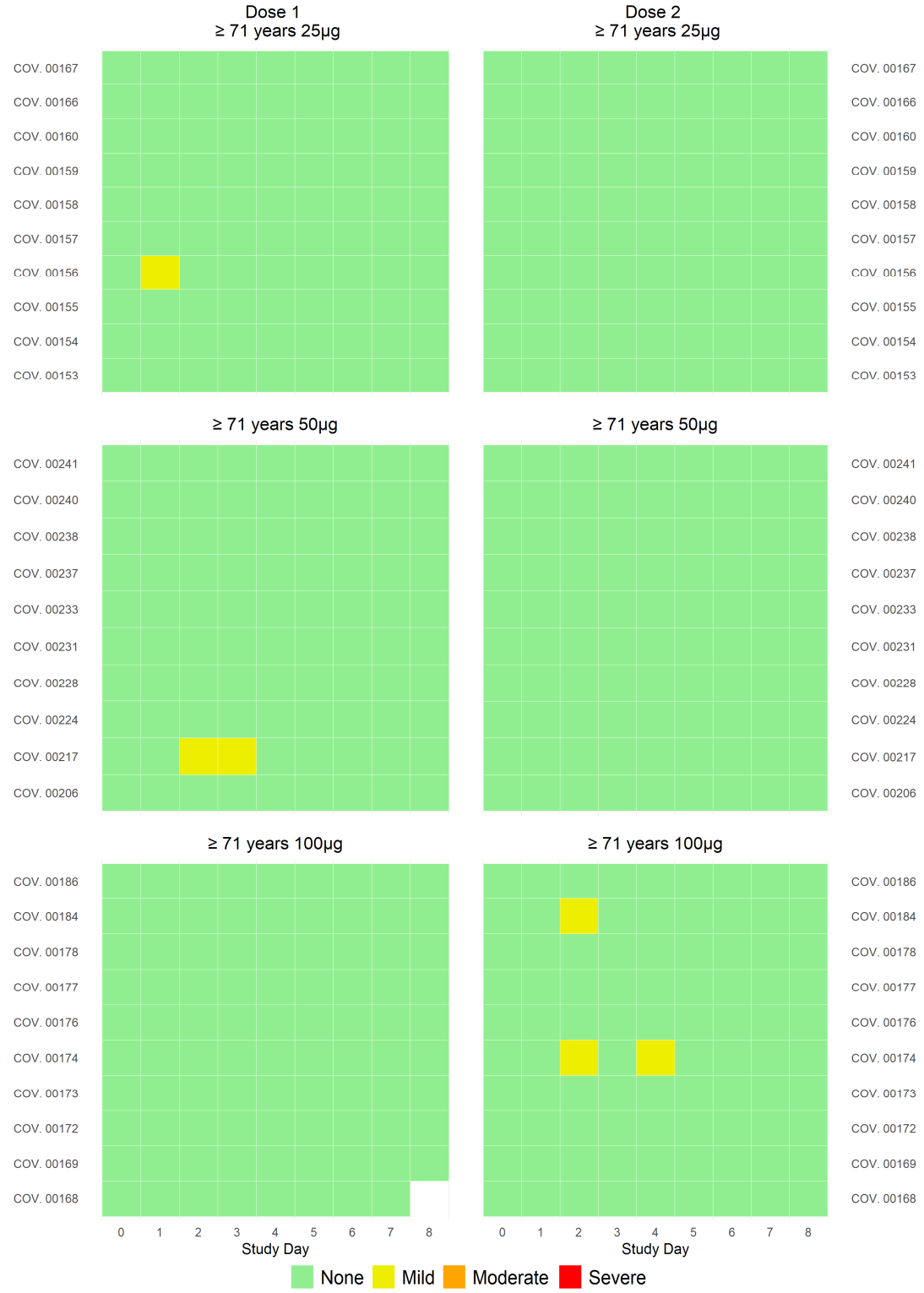


Figure 87: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Chills



Figure 88: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Chills



Figure 89: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Chills



Figure 90: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Erythema



Figure 91: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Erythema

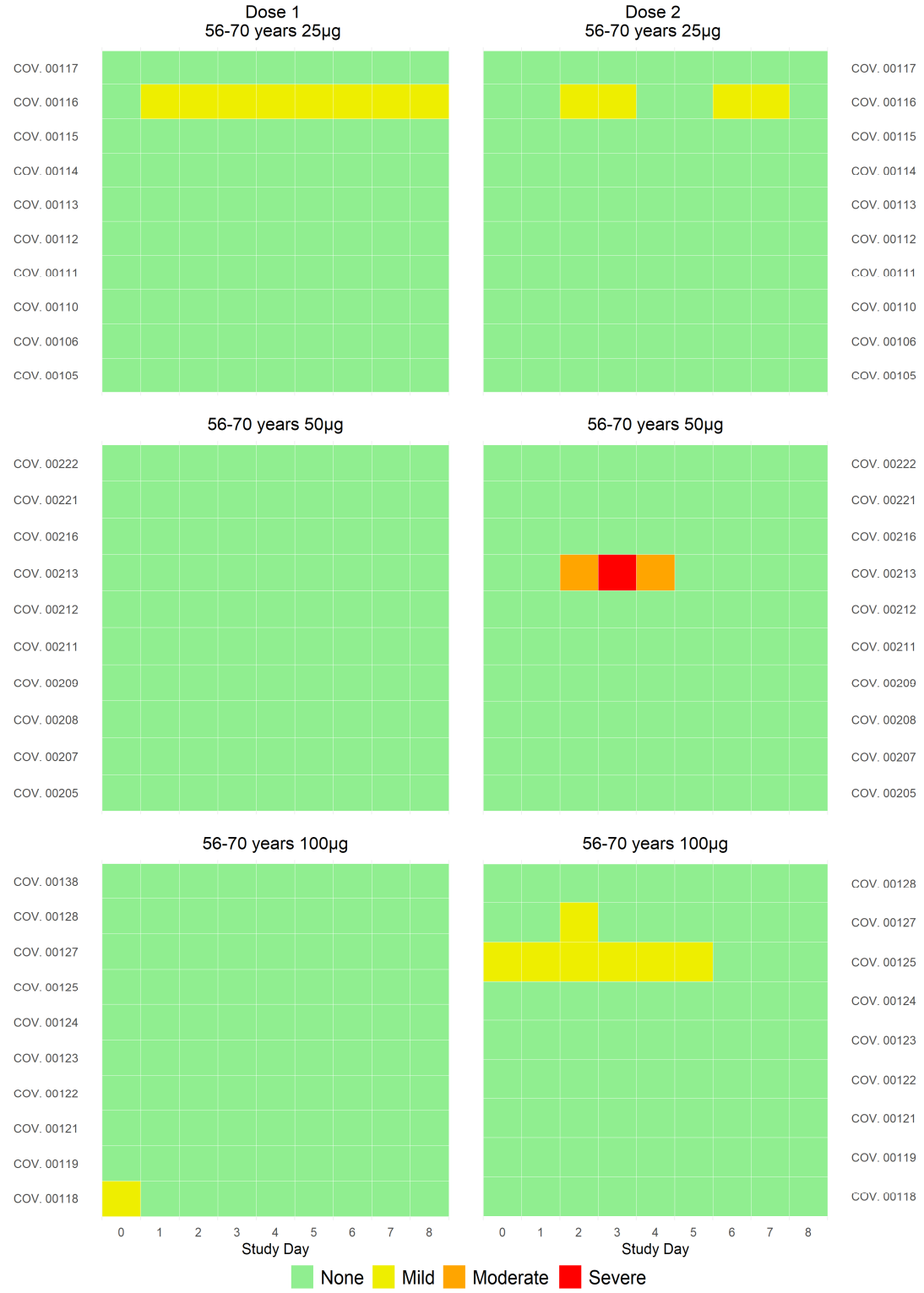


Figure 92: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Erythema

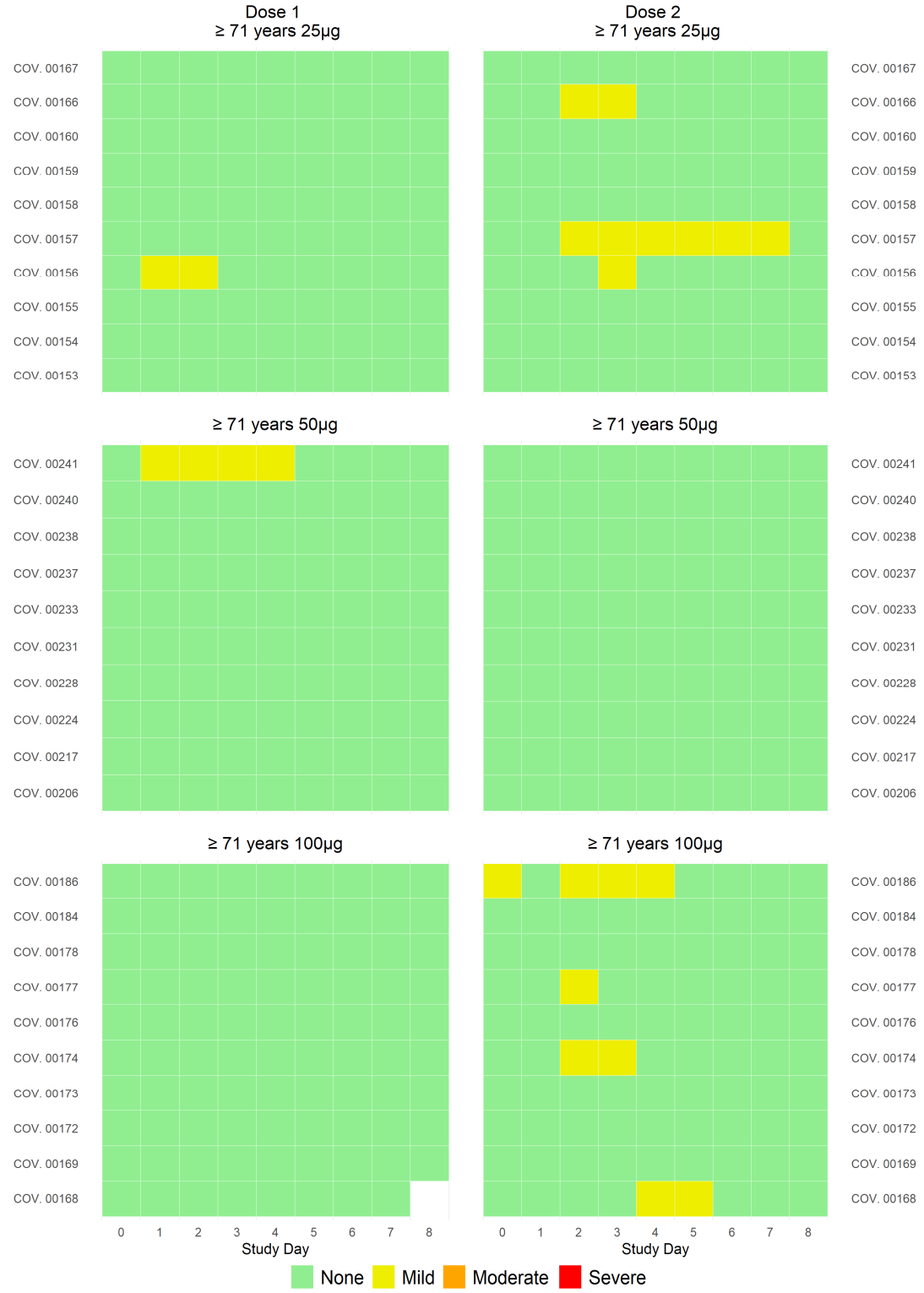


Figure 93: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Erythema (mm)



Figure 94: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Erythema (mm)

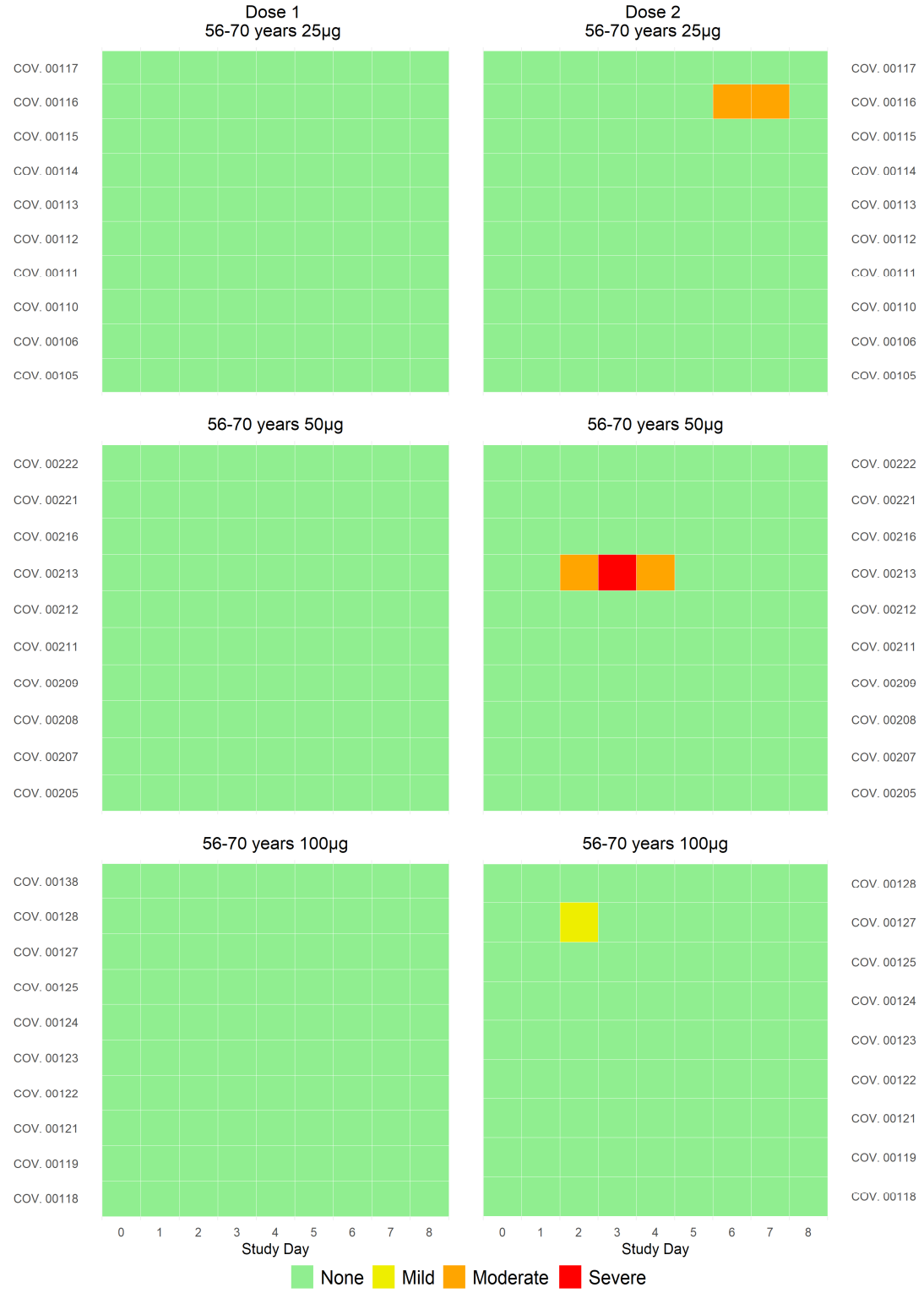


Figure 95: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Erythema (mm)



Figure 96: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Fatigue

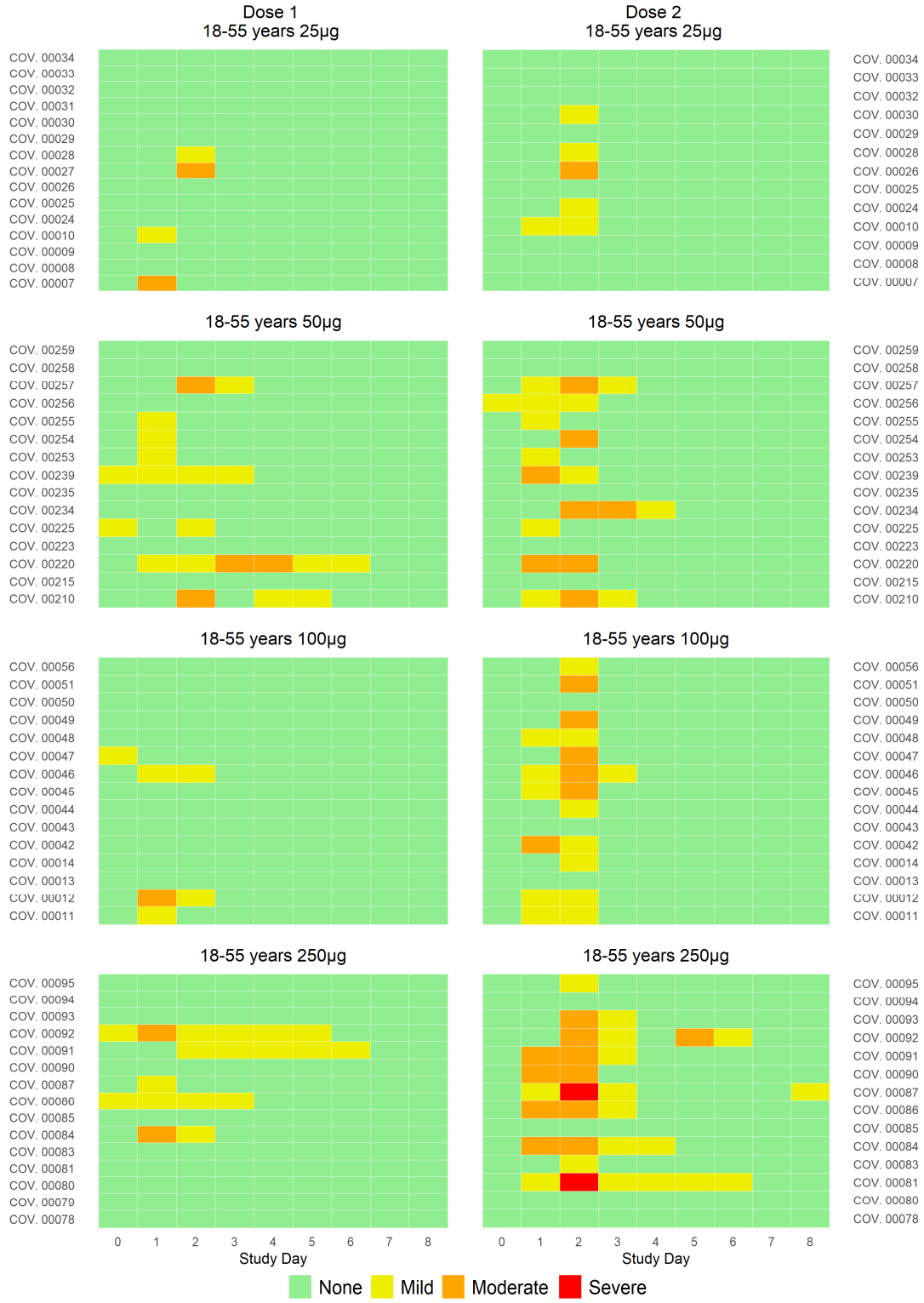


Figure 97: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Fatigue



Figure 98: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Fatigue

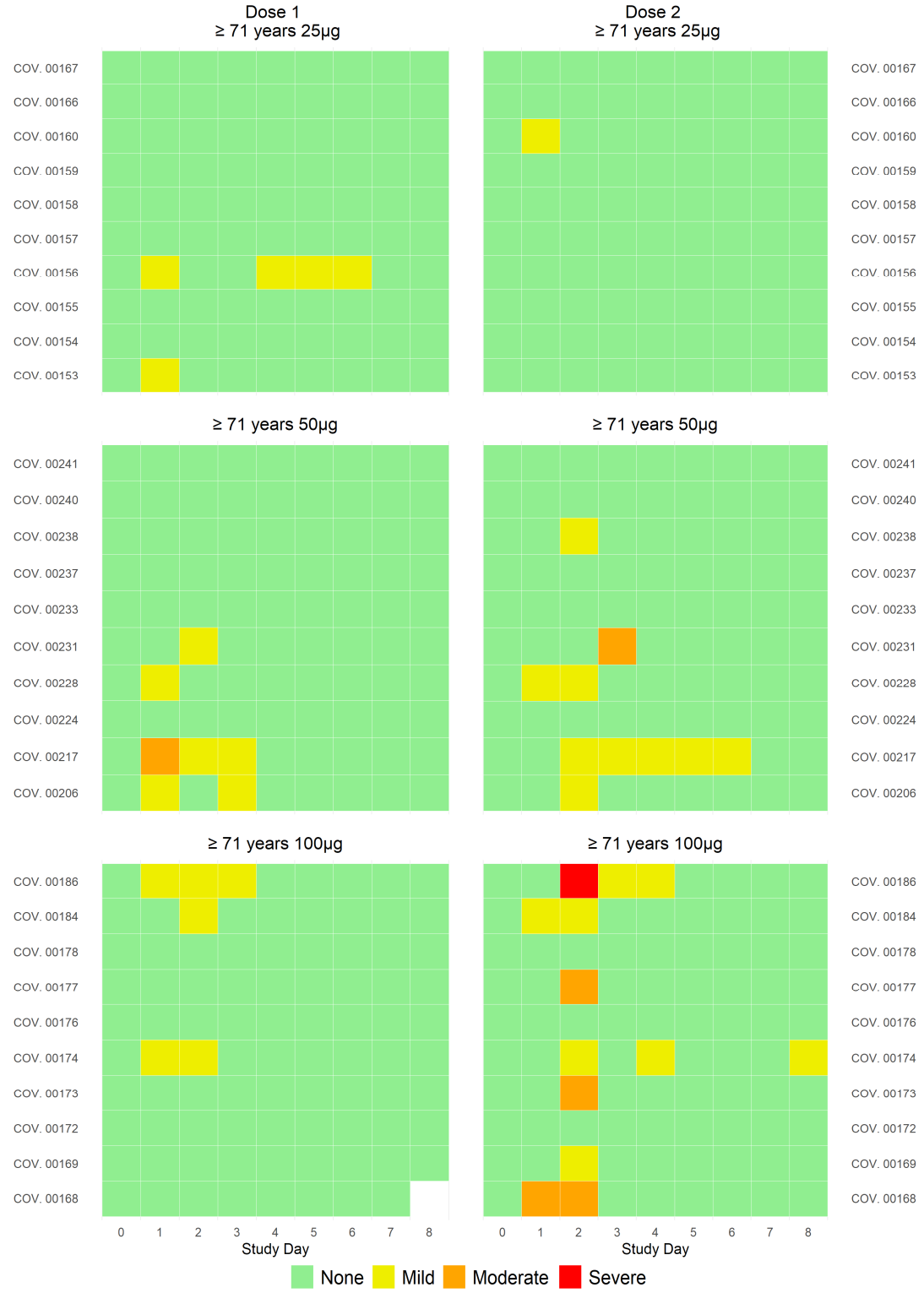


Figure 99: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Fever



Figure 100: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Fever

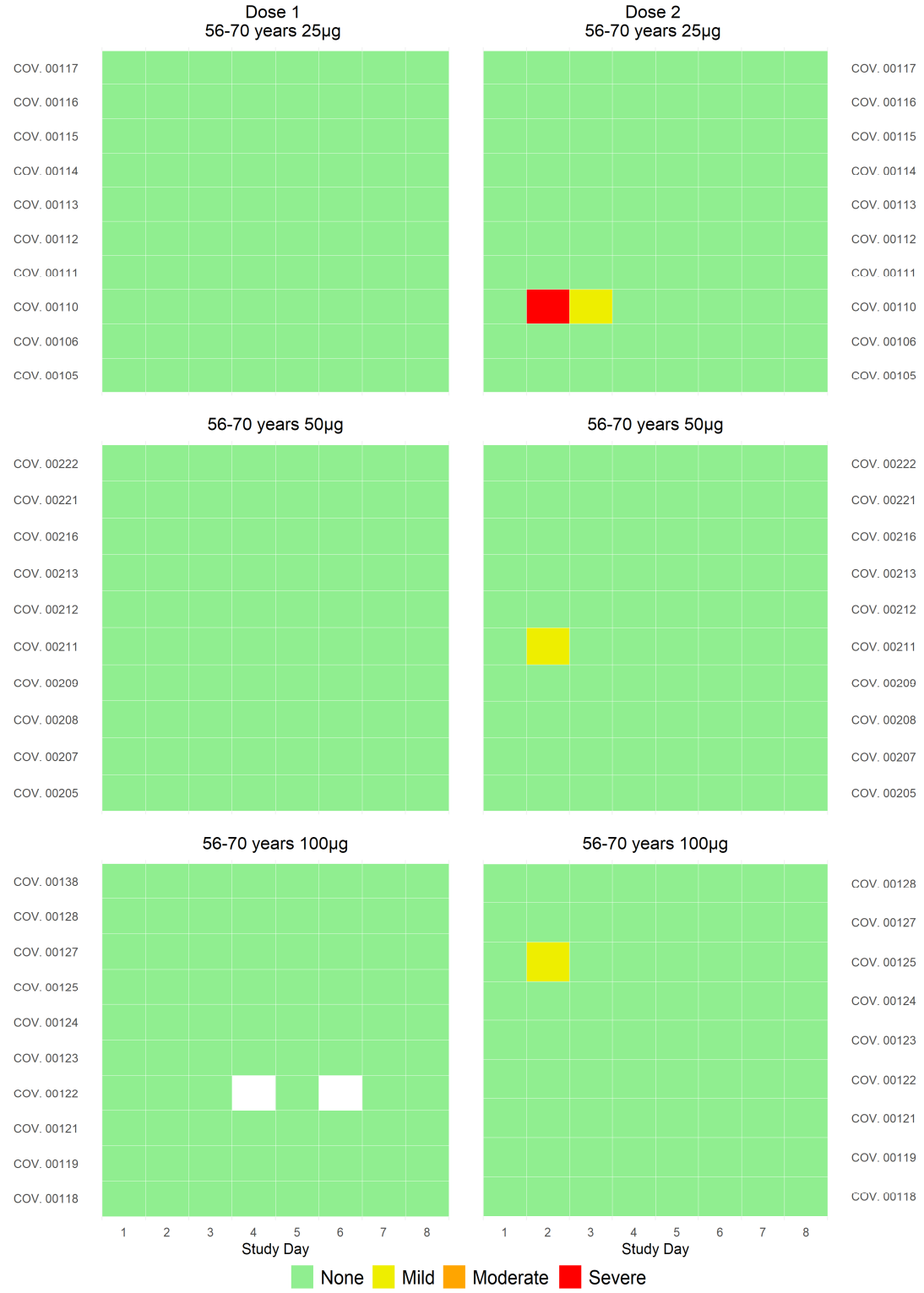


Figure 101: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Fever



Figure 102: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Headache



Figure 103: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Headache

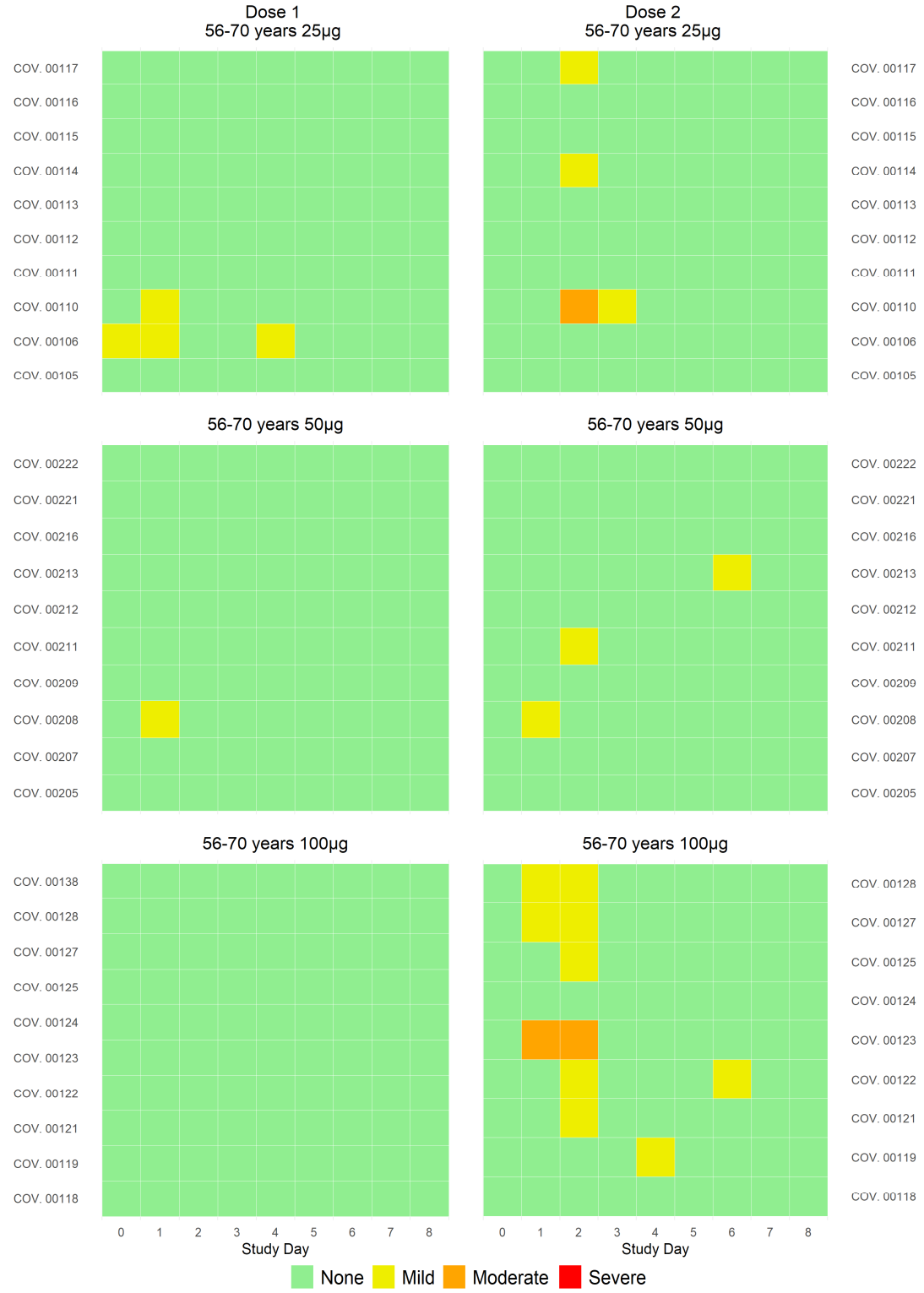


Figure 104: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Headache

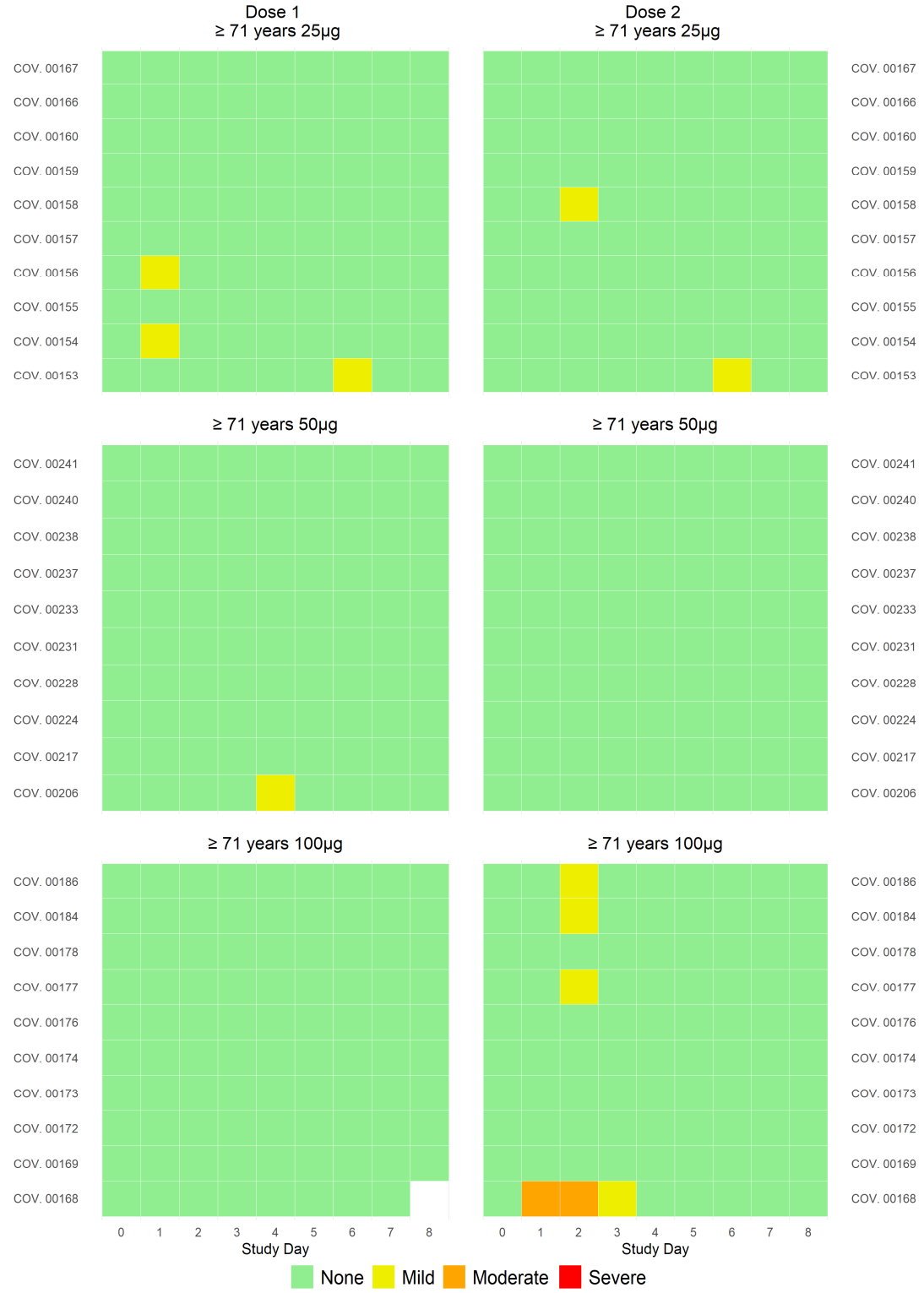


Figure 105: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Induration

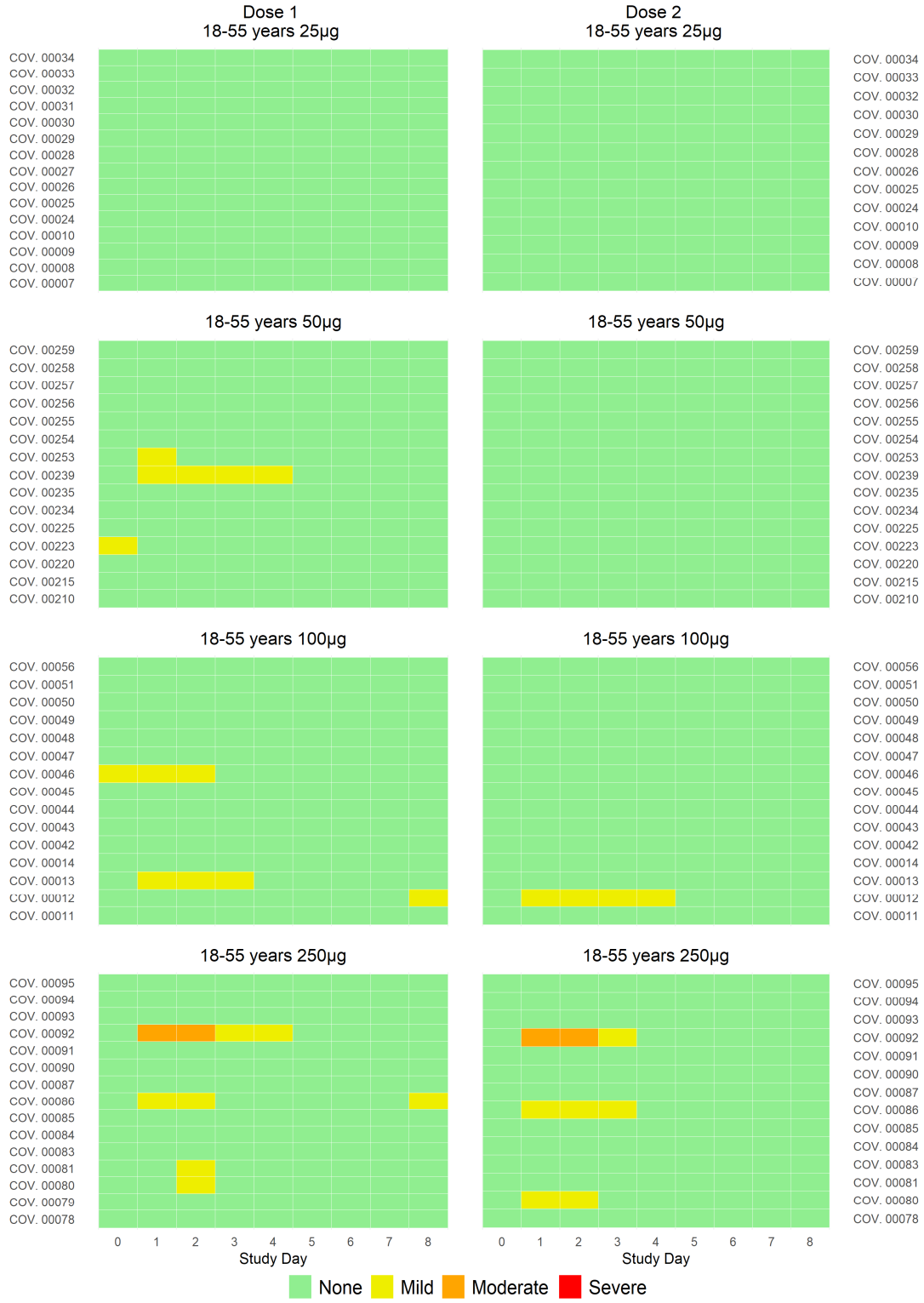


Figure 106: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Induration

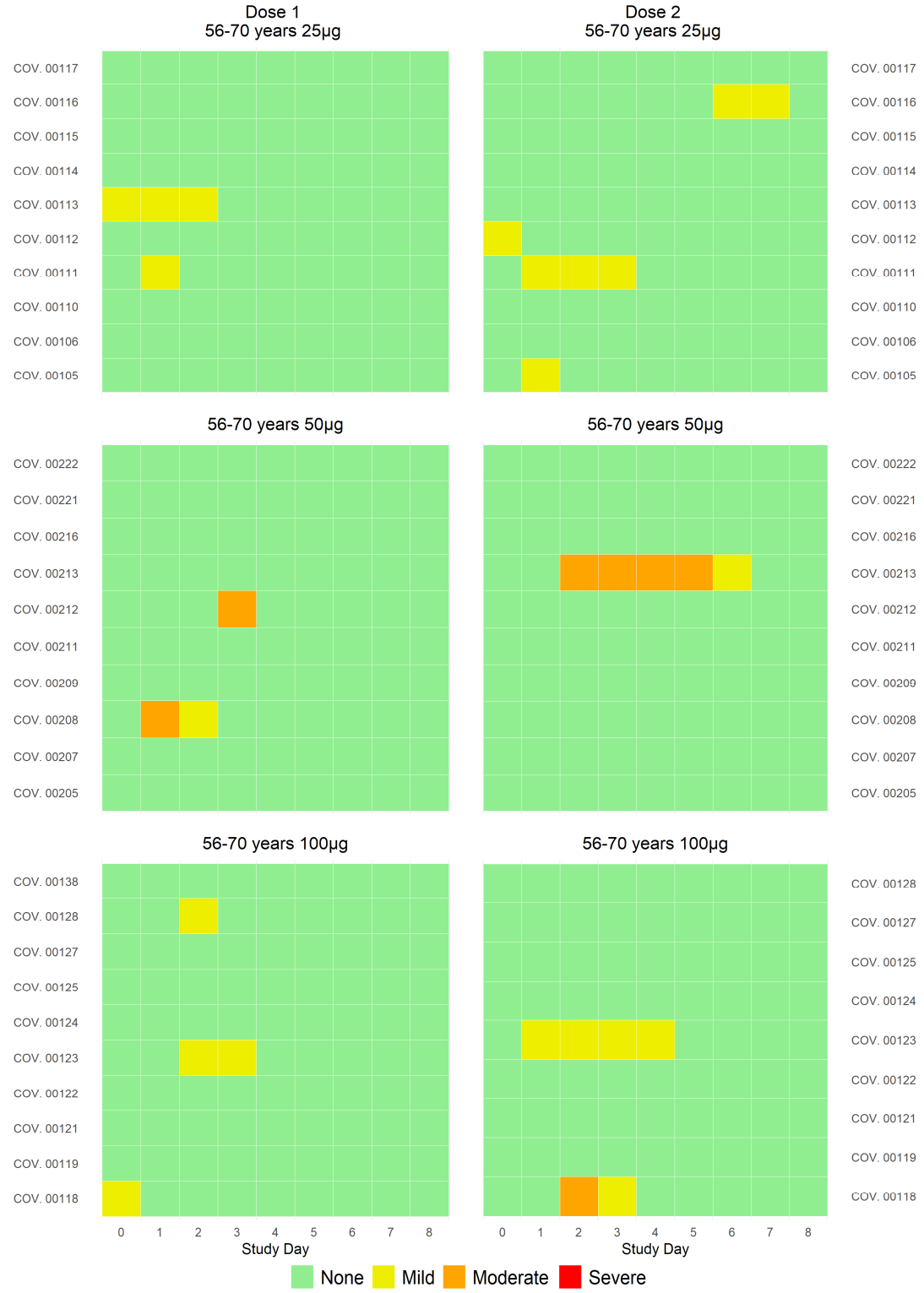


Figure 107: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Induration

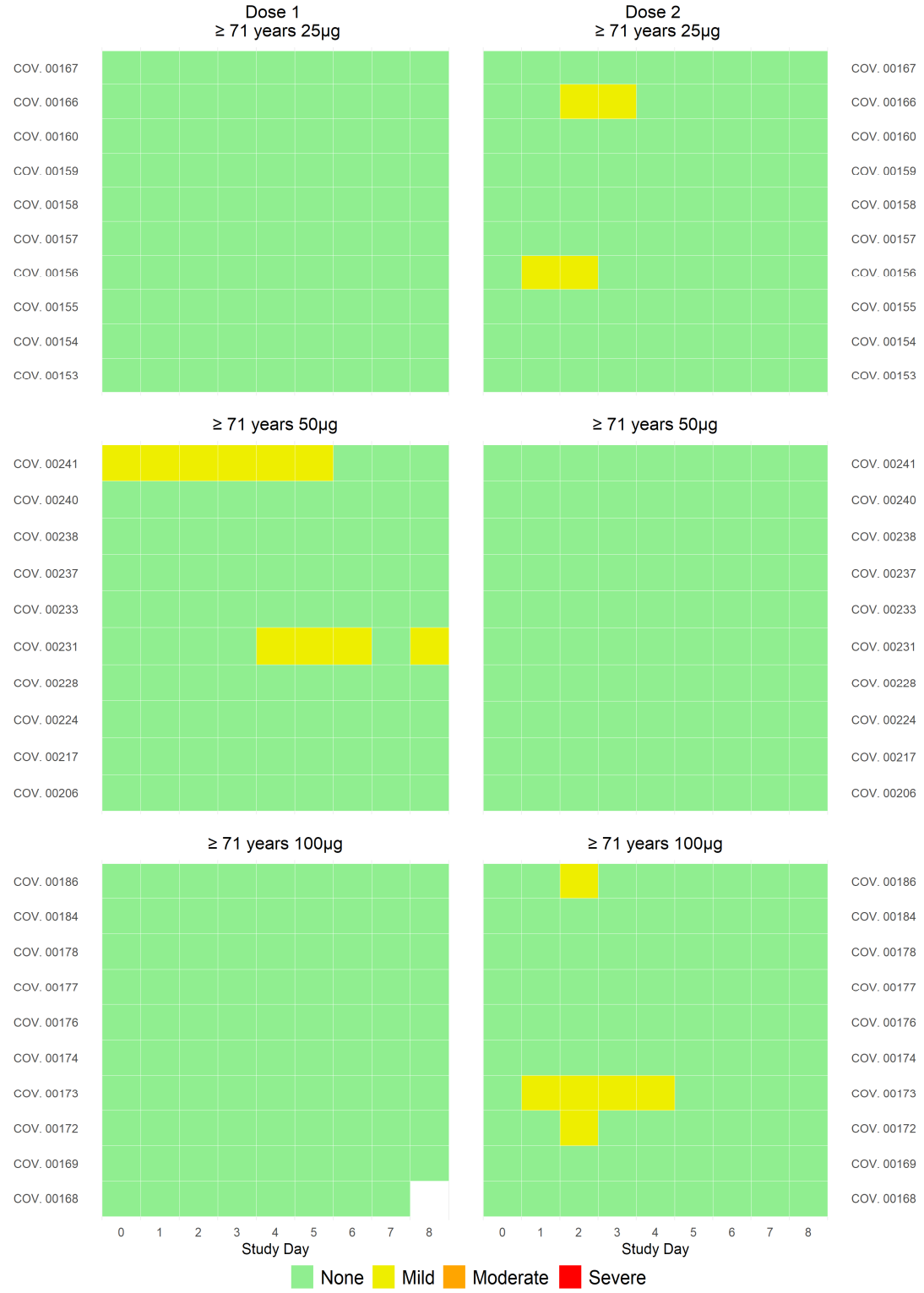


Figure 108: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Induration (mm)



Figure 109: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Induration (mm)

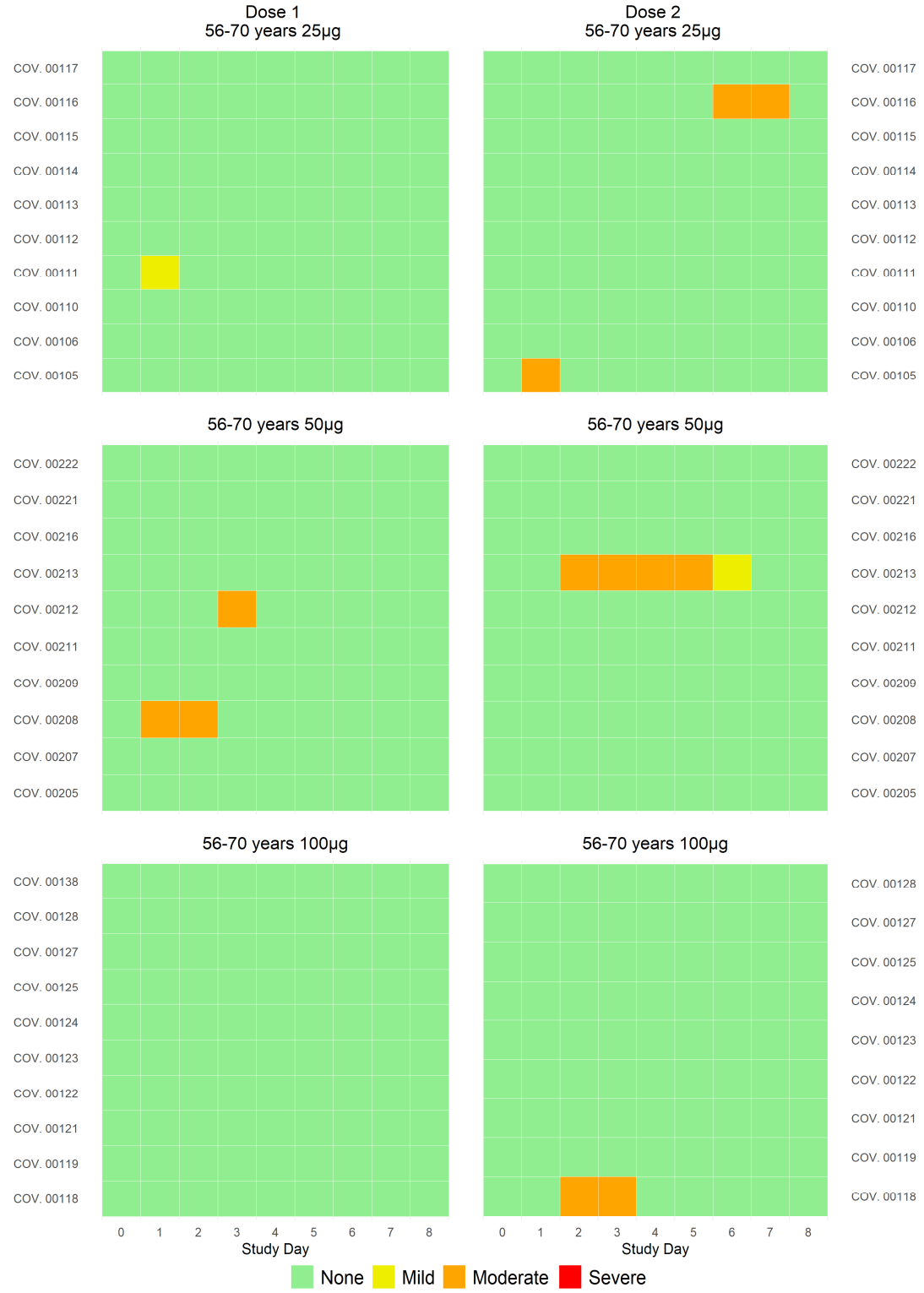


Figure 110: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Induration (mm)

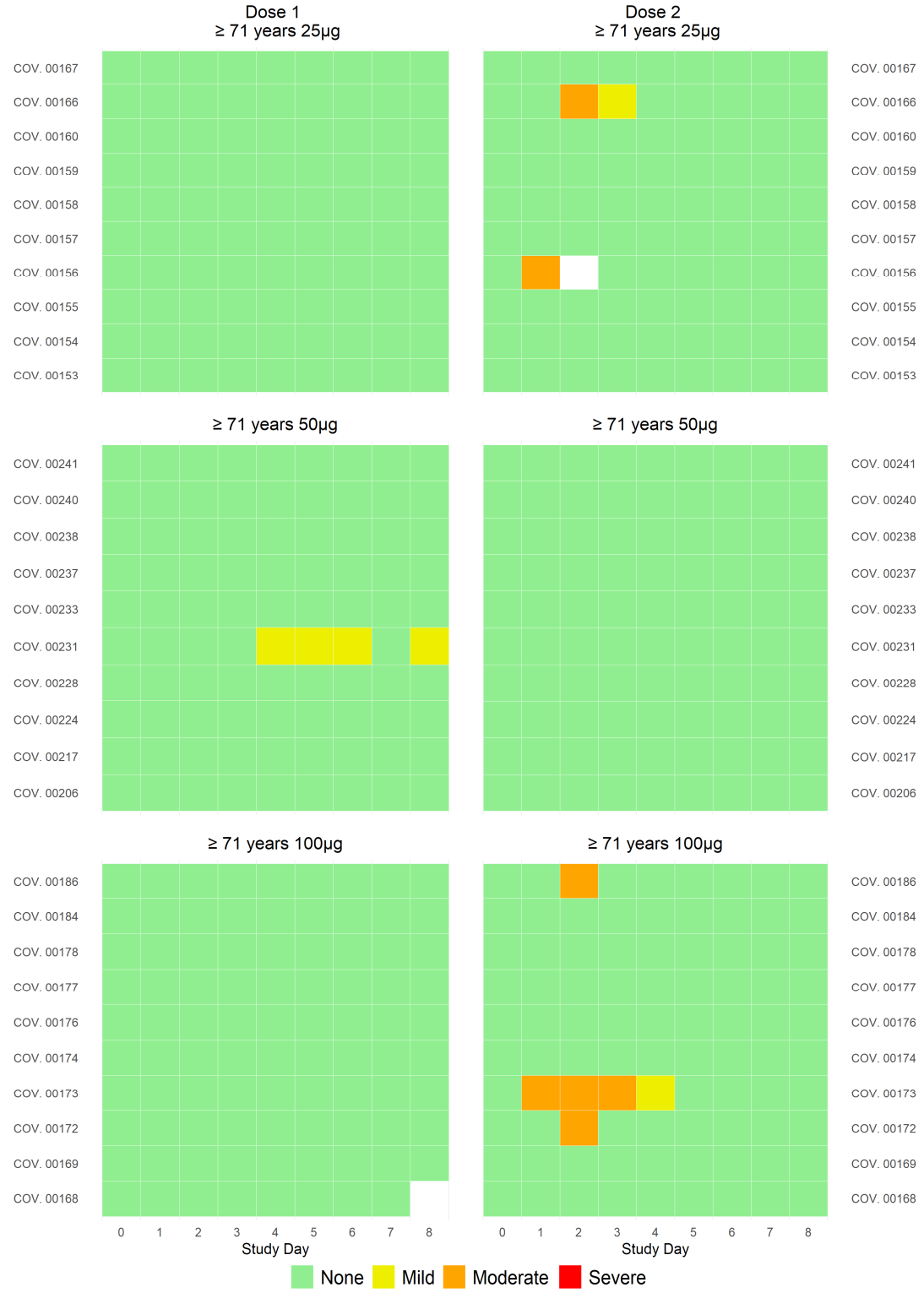


Figure 111: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Myalgia



Figure 112: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Myalgia

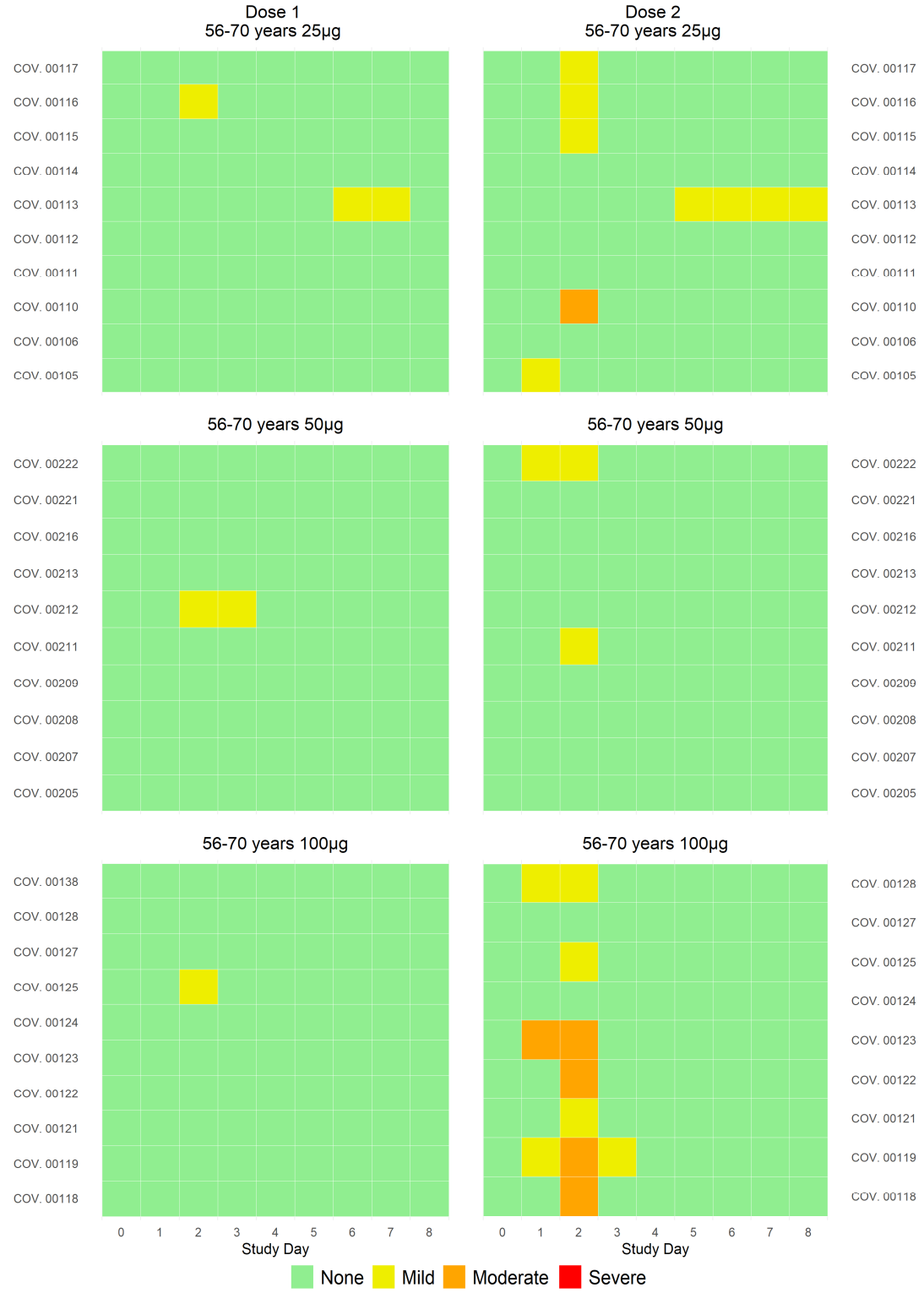


Figure 113: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Myalgia

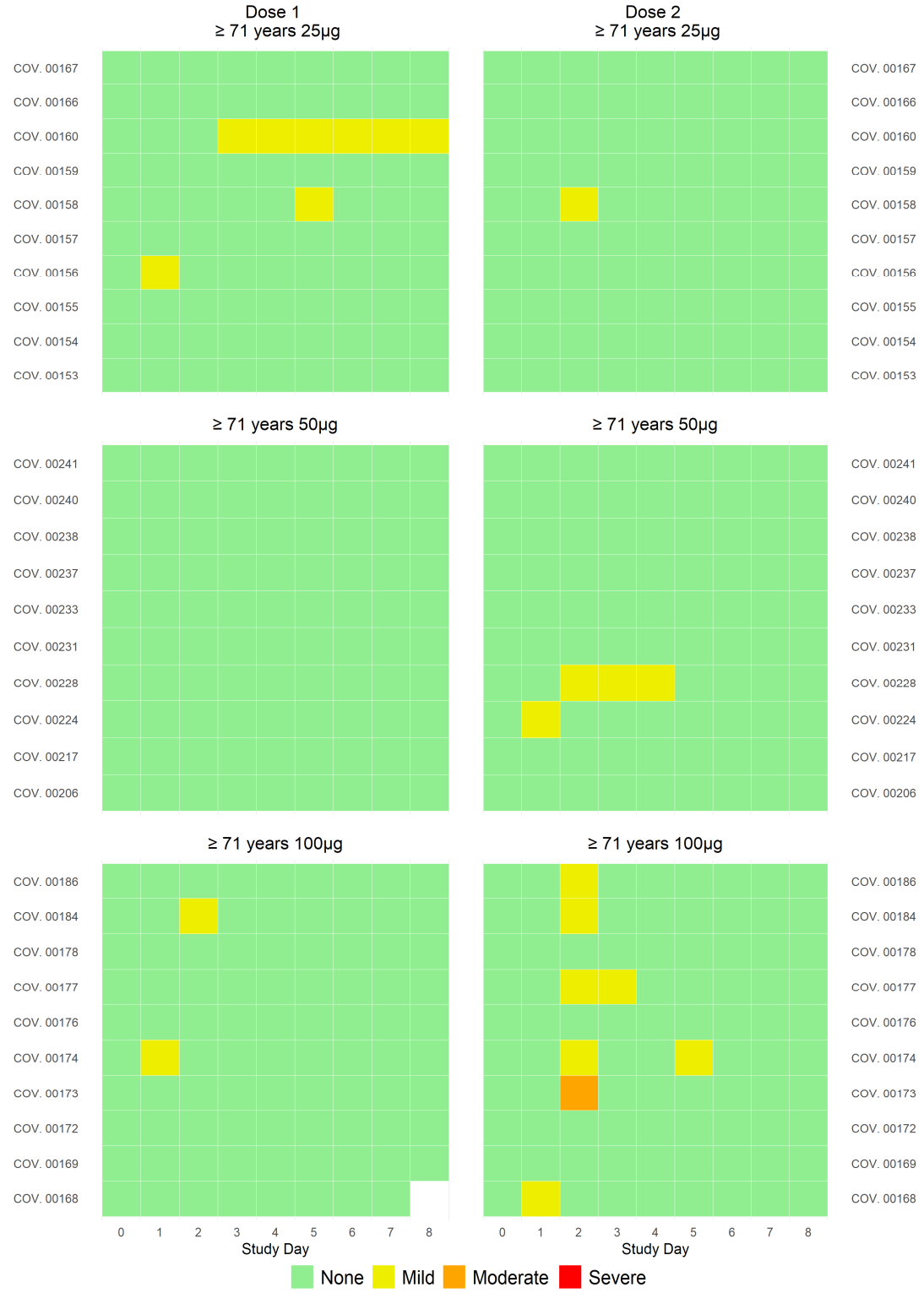


Figure 114: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Nausea



Figure 115: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Nausea



Figure 116: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Nausea



Figure 117: Solicited Symptoms by Days Post Vaccination and Treatment Group 18-55 Years of Age - Pain



Figure 118: Solicited Symptoms by Days Post Vaccination and Treatment Group 56-70 Years of Age - Pain

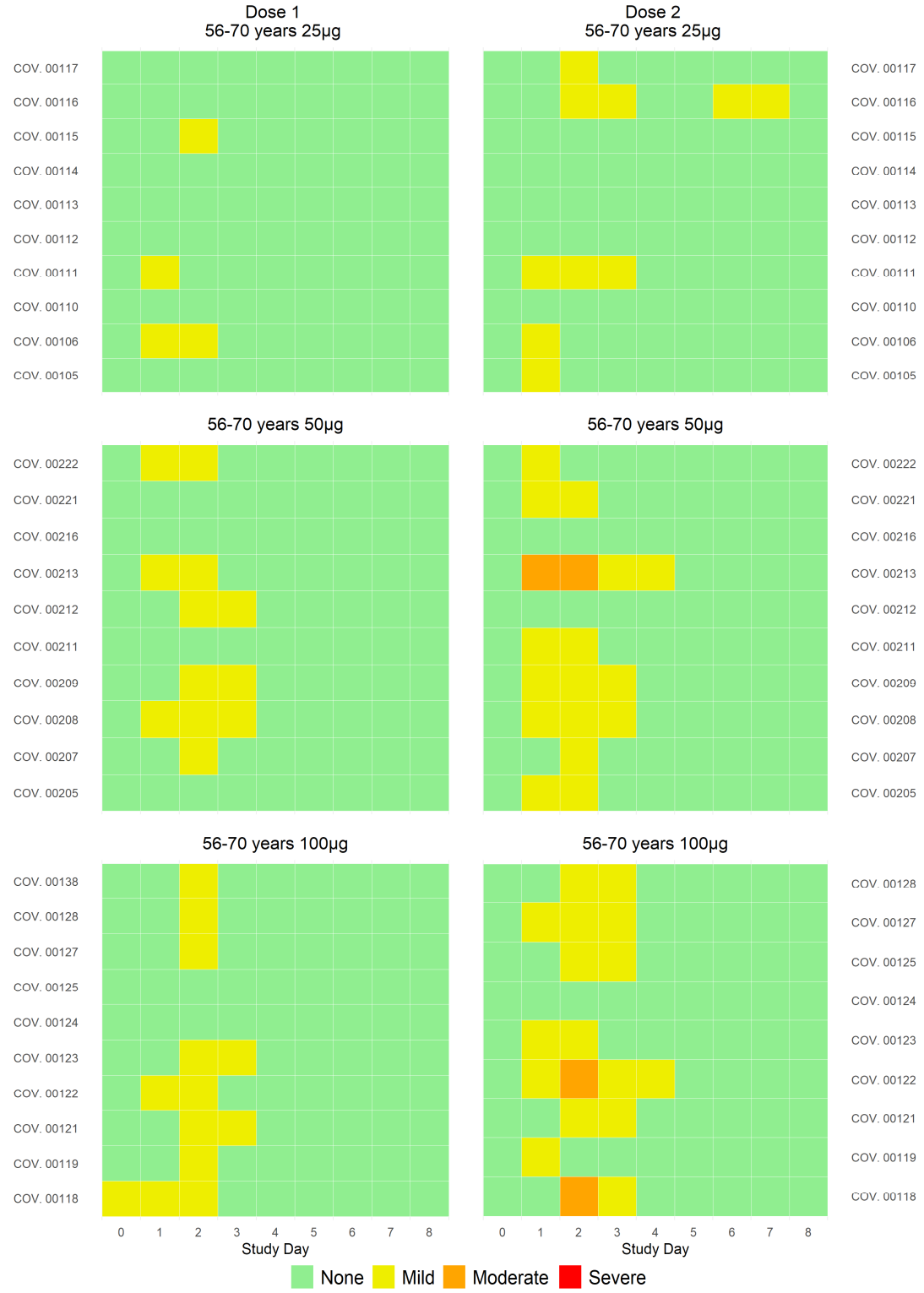


Figure 119: Solicited Symptoms by Days Post Vaccination and Treatment Group ≥71 Years of Age - Pain

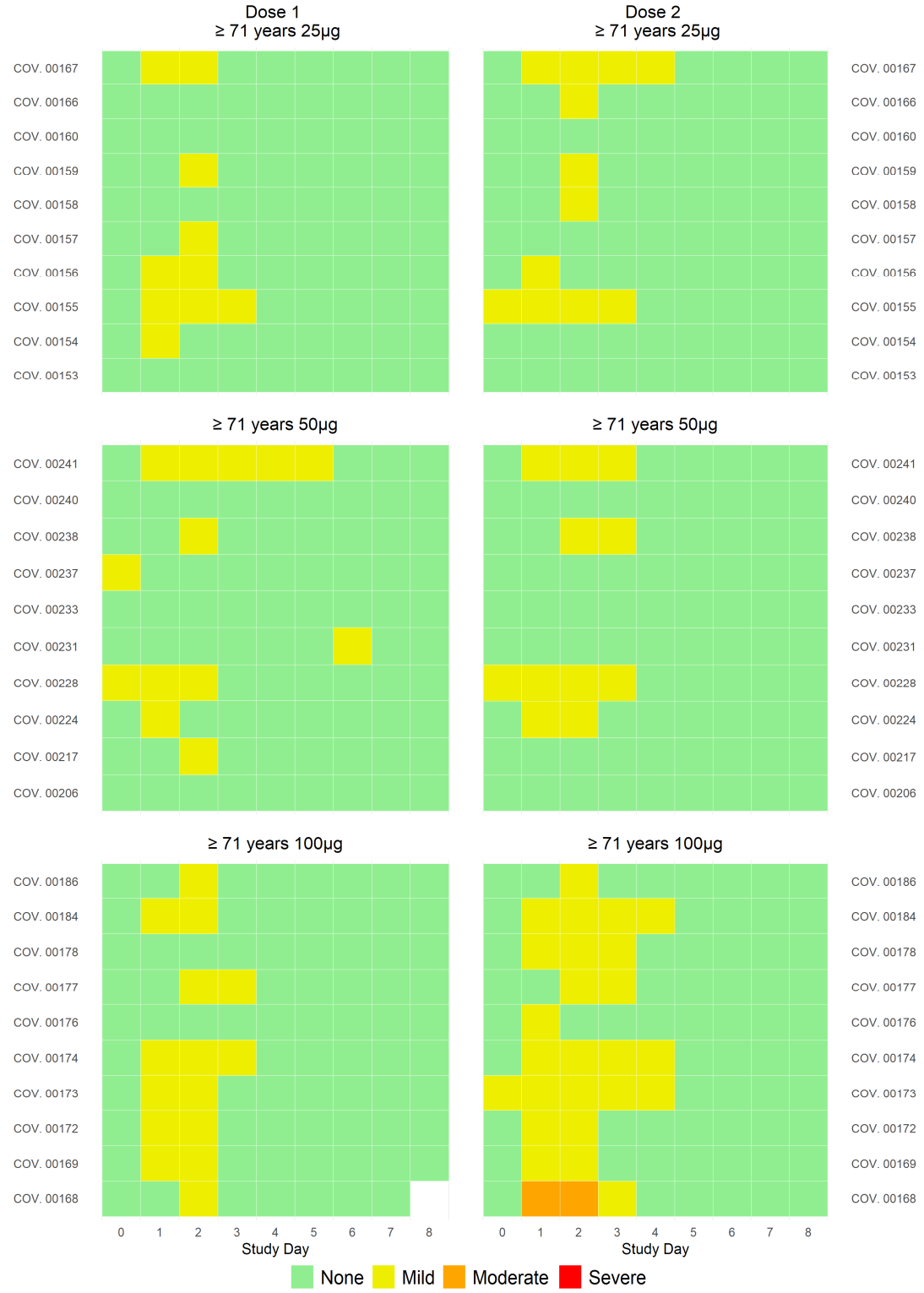


Figure 120: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity 18-55 Years of Age

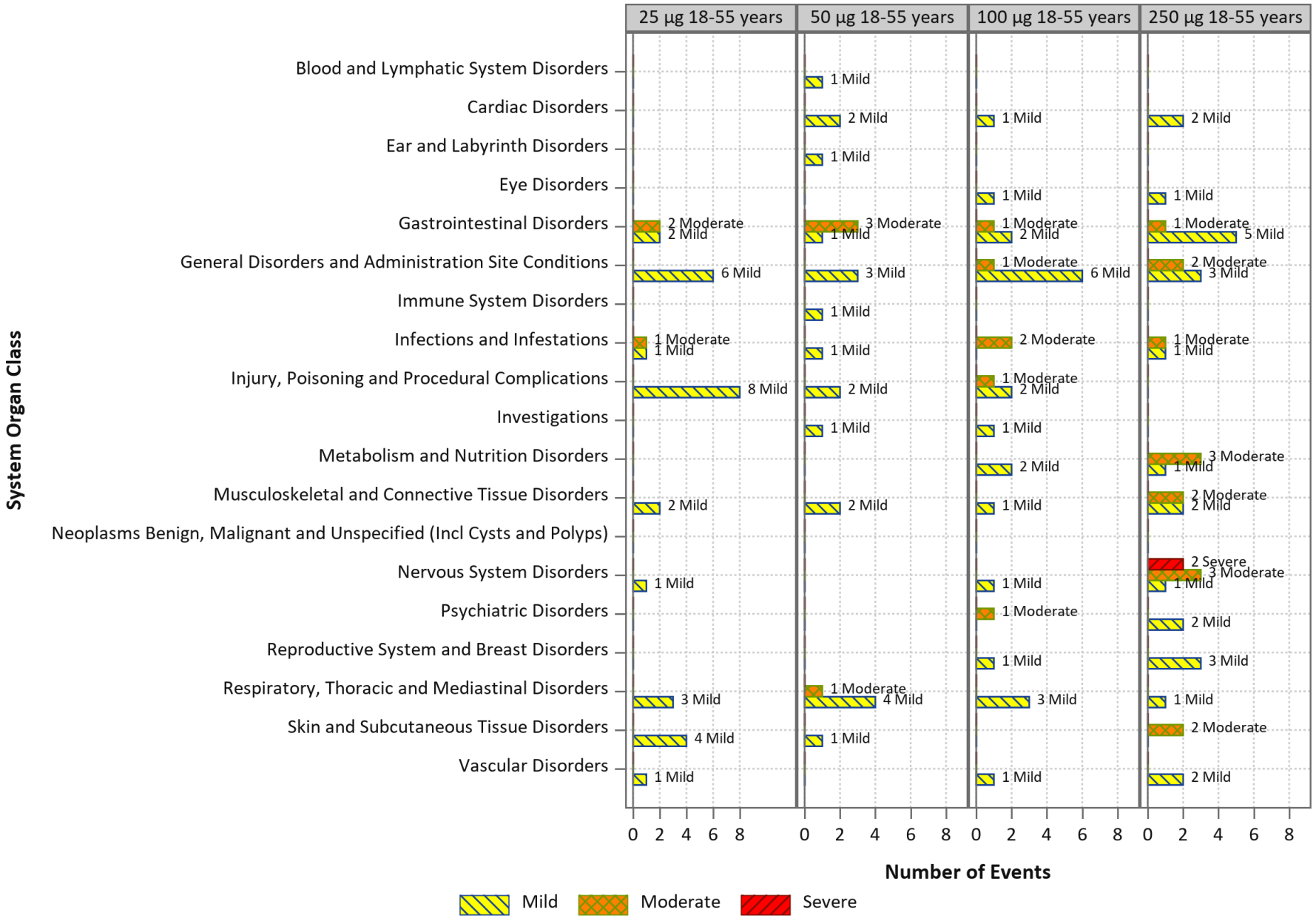

25 µg 18-55 years
50 µg 18-55 years
100 µg 18-55 years
250 µg 18-55 years
System Organ Class
Blood and Lymphatic System Disorders
Cardiac Disorders
Ear and Labyrinth Disorders
Eye Disorders
Gastrointestinal Disorders
General Disorders and Administration Site Conditions
Immune System Disorders
Infections and Infestations
Injury, Poisoning and Procedural Complications
Investigations
Metabolism and Nutrition Disorders
Musculoskeletal and Connective Tissue Disorders
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
Nervous System Disorders
Psychiatric Disorders
Reproductive System and Breast Disorders
Respiratory, Thoracic and Mediastinal Disorders
Skin and Subcutaneous Tissue Disorders
Vascular Disorders
1 Mild
2 Mild
1 Mild
2 Moderate
2 Mild
6 Mild
1 Moderate
1 Mild
8 Mild
2 Mild
1 Mild
3 Mild
4 Mild
1 Mild
3 Moderate
1 Mild
3 Mild
1 Mild
1 Mild
2 Mild
1 Mild
2 Mild
1 Moderate
4 Mild
1 Mild
1 Mild
1 Moderate
2 Mild
1 Moderate
6 Mild
2 Moderate
1 Moderate
2 Mild
1 Mild
2 Mild
1 Mild
1 Moderate
1 Mild
3 Mild
1 Mild
2 Mild
1 Mild
1 Moderate
5 Mild
2 Moderate
3 Mild
1 Moderate
1 Mild
3 Moderate
1 Mild
2 Moderate
2 Mild
2 Severe
3 Moderate
1 Mild
2 Mild
3 Mild
1 Mild
2 Moderate
2 Mild
0 2 4 6 8
Number of Events
Mild
Moderate
Severe

Figure 121: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity 56-70 Years of Age


25 µg 56-70 years
50 µg 56-70 years
100 µg 56-70 years
System Organ Class
Blood and Lymphatic System Disorders
Cardiac Disorders
Ear and Labyrinth Disorders
Eye Disorders
Gastrointestinal Disorders
General Disorders and Administration Site Conditions
Immune System Disorders
Infections and Infestations
Injury, Poisoning and Procedural Complications
Investigations
Metabolism and Nutrition Disorders
Musculoskeletal and Connective Tissue Disorders
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
Nervous System Disorders
Psychiatric Disorders
Reproductive System and Breast Disorders
Respiratory, Thoracic and Mediastinal Disorders
Skin and Subcutaneous Tissue Disorders
Vascular Disorders
2 Mild
1 Moderate
2 Moderate
1 Moderate
1 Moderate
1 Mild
1 Moderate
2 Mild
1 Mild
1 Mild
2 Mild
1 Moderate
1 Severe
1 Moderate
1 Moderate
2 Mild
1 Mild
1 Mild
1 Moderate
1 Mild
1 Severe
1 Mild
1 Moderate
1 Mild
2 Moderate
1 Mild
0 2 4 6 8
Number of Events
Mild
Moderate
Severe

Figure 122: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity ≥71 years of Age

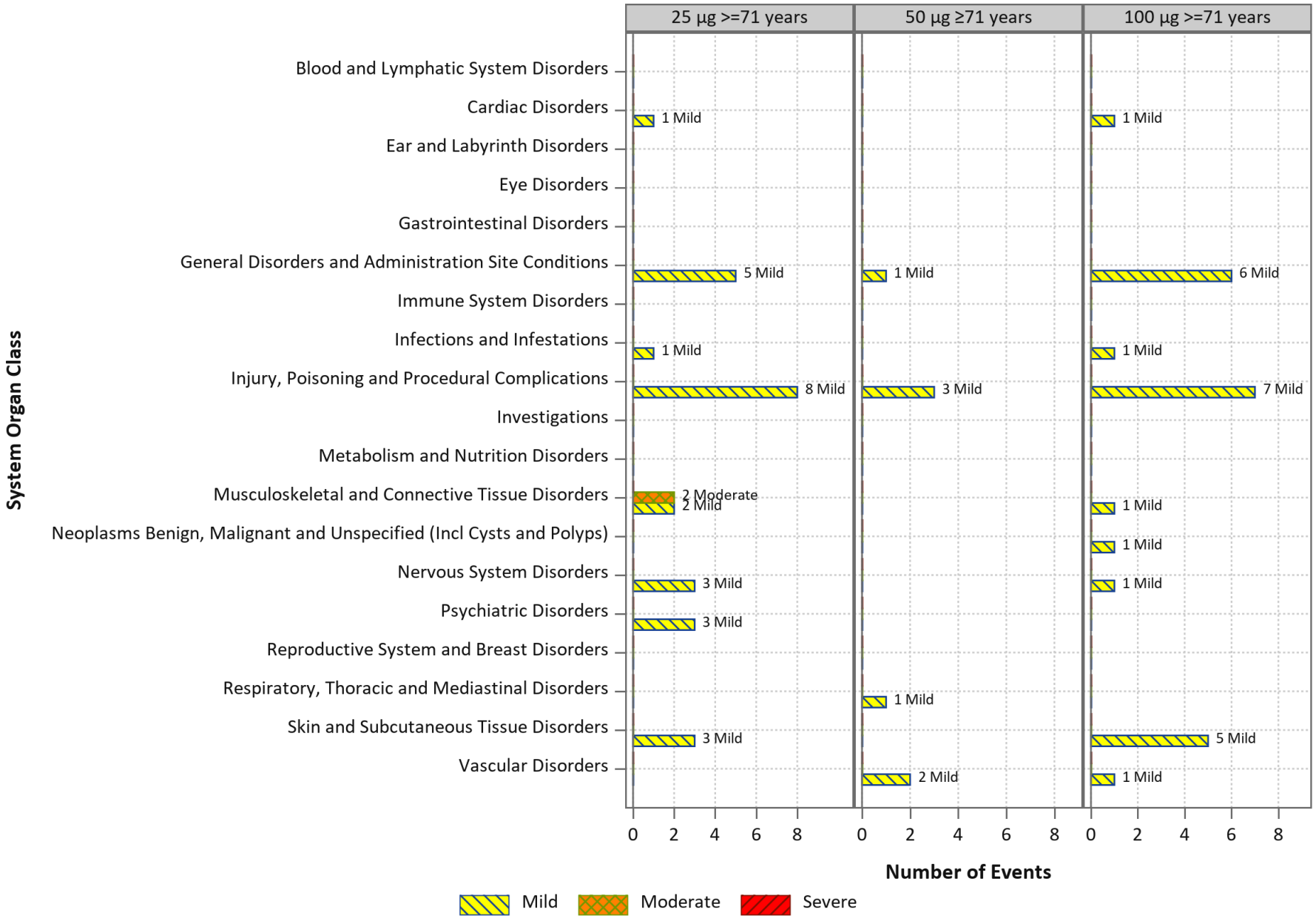

25 µg >=71 years
50 µg ≥71 years
100 µg >=71 years
System Organ Class
Blood and Lymphatic System Disorders
Cardiac Disorders
Ear and Labyrinth Disorders
Eye Disorders
Gastrointestinal Disorders
General Disorders and Administration Site Conditions
Immune System Disorders
Infections and Infestations
Injury, Poisoning and Procedural Complications
Investigations
Metabolism and Nutrition Disorders
Musculoskeletal and Connective Tissue Disorders
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)
Nervous System Disorders
Psychiatric Disorders
Reproductive System and Breast Disorders
Respiratory, Thoracic and Mediastinal Disorders
Skin and Subcutaneous Tissue Disorders
Vascular Disorders
1 Mild
5 Mild
1 Mild
8 Mild
2 Moderate
2 Mild
3 Mild
3 Mild
3 Mild
1 Mild
1 Mild
6 Mild
1 Mild
3 Mild
7 Mild
1 Mild
1 Mild
1 Mild
5 Mild
1 Mild
2 Mild
0 2 4 6 8
Number of Events
Mild
Moderate
Severe

TABLE 126:
Listing of Serious Adverse Events

No serious adverse events have been reported.

TABLE 127:
Listing of MAAEs and NOCMCs

Subject ID	Treatment Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	Duration of Event	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00046	100 µg (18-55 years)	Gastroenteritis	02	24APR2020	78 (1)	11JUL2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00046	100 µg (18-55 years)	Worsening ADHD Symptoms	02	24APR2020	21 (61)	15MAY2020	Psychiatric disorders	Yes	No	Not related	Recovered /resolved
COV.00050	100 µg (18-55 years)	Infected Cyst	02	24APR2020	61 (9)	24JUN2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00092	250 µg (18-55 years)	Worsening Vaginal Itching	01	14APR2020	6 (34)	20APR2020	Reproductive system and breast disorders	Yes	No	Not related	Recovered /resolved
COV.00091	250 µg (18-55 years)	Abdominal Discomfort	02	12MAY2020	26 (10)	07JUN2020	Gastrointestinal disorders	Yes	No	Related	Recovered /resolved
COV.00111	25 µg (56-70 years)	Worsening Toenail Fungus	01	20APR2020	25 (Ongoing)	15MAY2020	Infections and infestations	Yes	No	Not related	Recovering /resolving
COV.00114	25 µg (56-70 years)	Decreased Bone Density	02	18MAY2020	28 (Ongoing)	15JUN2020	Investigations	Yes	Yes	Not related	Recovering /resolving
COV.00114	25 µg (56-70 years)	Worsening of Sciatica	02	18MAY2020	56 (39)	13JUL2020	Nervous system disorders	Yes	No	Not related	Recovered /resolved
COV.00138	100 µg (56-70 years)	Paronychia	01	23APR2020	2 (13)	25APR2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00138	100 µg (56-70 years)	Contact Dermatitis	01	23APR2020	111 (26)	12AUG2020	Skin and subcutaneous tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00138	100 µg (56-70 years)	Maculopapular Rash	01	23APR2020	9 (21)	02MAY2020	Skin and subcutaneous tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00234	50 µg (18-55 years)	Abdominal Pain	01	04JUN2020	17 (3)	21JUN2020	Gastrointestinal disorders	Yes	No	Not related	Recovered /resolved

Subject ID	Treatment Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	Duration of Event	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00009	25 µg (18-55 years)	Hordeolum Exacerbation	02	14APR2020	55 (Ongoing)	08JUN2020	Infections and infestations	Yes	No	Not related	
COV.00009	25 µg (18-55 years)	Jaw Pain	02	14APR2020	36 (61)	20MAY2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00010	25 µg (18-55 years)	Infected Pustules	02	14APR2020	47 (42)	31MAY2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00032	25 µg (18-55 years)	Contusions	02	21APR2020	74 (12)	04JUL2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00026	25 µg (18-55 years)	Puncture Wound	02	21APR2020	72 (26)	02JUL2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00079	250 µg (18-55 years)	Anal Fissure	01	08APR2020	56 (21)	03JUN2020	Gastrointestinal disorders	Yes	No	Not related	Recovered /resolved
COV.00079	250 µg (18-55 years)	UTI	01	08APR2020	133 (2)	19AUG2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00079	250 µg (18-55 years)	Vaginal Itching	01	08APR2020	56 (18)	03JUN2020	Reproductive system and breast disorders	Yes	No	Not related	Recovered /resolved
COV.00079	250 µg (18-55 years)	Sore Throat	01	08APR2020	24 (3)	02MAY2020	Respiratory, thoracic and mediastinal disorders	Yes	No	Not related	Recovered /resolved
COV.00081	250 µg (18-55 years)	Epididymitis	02	05MAY2020	29 (16)	03JUN2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00169	100 µg (≥71 years)	Chipped Tooth	02	02JUN2020	3 (76)	05JUN2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved

Subject ID	Treatment Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	Duration of Event	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00167	25 µg (≥71 years)	Exacerbation of Arthritis	01	05MAY2020	27 (62)	01JUN2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00186	100 µg (≥71 years)	UTI	02	08JUN2020	58 (3)	05AUG2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00177	100 µg (≥71 years)	Squamous Cell Carcinoma	02	08JUN2020	79 (0)	26AUG2020	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Yes	No	Not related	Recovered /resolved
COV.00254	50 µg (18-55 years)	Vertigo	02	13JUL2020	77 (0)	28SEP2020	Ear and labyrinth disorders	Yes	No	Not related	Recovered /resolved
COV.00256	50 µg (18-55 years)	Exacerbation of Impacted Wisdom Teeth	02	13JUL2020	2 (5)	15JUL2020	Gastrointestinal disorders	Yes	No	Not related	Recovered /resolved
COV.00240	50 µg (≥71 years)	Traumatic Injuries	01	05JUN2020	19 (21)	24JUN2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00240	50 µg (≥71 years)	Tick Bite	02	01JUL2020	35 (22)	05AUG2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00208	50 µg (56-70 years)	Viral Syndrome	02	02JUL2020	40 (27)	11AUG2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00221	50 µg (56-70 years)	Cracked Tooth	02	30JUN2020	80 (Ongoing)	18SEP2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovering /resolving
COV.00222	50 µg (56-70 years)	Urinary Tract Infection	02	30JUN2020	31 (40)	31JUL2020	Infections and infestations	Yes	No	Not related	Recovered /resolved

[a]Date of most recent dose/product administration.
[b]Related, Not Related.

Table 128: Laboratory Results by Parameter, Severity, and Study Day
Any Chemistry Parameter

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	14	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	14	93	-	-	1	7	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	57	95	2	3	1	2	-	-
	25 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	28	93	1	3	-	-	1	3
	All Subjects	120	120	114	95	4	3	1	1	1	1
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	12	86	2	14	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	56	95	3	5	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	2	7	-	-	1	3
	All Subjects	120	119	113	95	5	4	-	-	1	1
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	14	93	-	-	1	7	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	12	80	3	20	-	-	-	-
	250 µg (18-55 years)	15	14	13	93	1	7	-	-	-	-
	All Subjects (18-55 years)	60	59	54	92	4	7	1	2	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	113	95	5	4	1	1	-	-
	25 µg (18-55 years)	15	15	13	87	2	13	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	-	-	1	7	-	-
	All Subjects (18-55 years)	60	60	56	93	3	5	1	2	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	115	96	4	3	1	1	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	12	80	2	13	1	7	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	11	73	4	27	-	-	-	-
	250 µg (18-55 years)	15	15	13	87	1	7	-	-	1	7
	All Subjects (18-55 years)	60	60	51	85	7	12	1	2	1	2
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	8	80	2	20	-	-	-	-
	All Subjects (56-70 years)	30	30	28	93	2	7	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	2	7	-	-	1	3
	All Subjects	120	120	106	88	11	9	1	1	2	2

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 129: Laboratory Results by Parameter, Severity, and Study Day
Serum Creatinine

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	14	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	119	100	-	-	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	119	100	-	-	-	-	-	-
	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-

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 130: Laboratory Results by Parameter, Severity, and Study Day
Alanine Aminotransferase

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	14	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	58	97	2	3	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	118	98	2	2	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	13	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	57	97	2	3	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	117	98	2	2	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	58	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	118	99	1	1	-	-	-	-
	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	14	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	13	87	2	13	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	57	95	3	5	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	117	98	3	3	-	-	-	-

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 131: Laboratory Results by Parameter, Severity, and Study Day
Aspartate Aminotransferase

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	14	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	119	100	-	-	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	118	99	1	1	-	-	-	-
	25 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	59	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	119	99	1	1	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	14	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	59	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	118	98	2	2	-	-	-	-

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 132: Laboratory Results by Parameter, Severity, and Study Day
Alkaline Phosphatase

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	Treatment Group	N	N*	n	%	n	%	n	%	n	%
Screening (Day -42 to -1)	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	14	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	119	100	-	-	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	119	100	-	-	-	-	-	-
	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-

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 133: Laboratory Results by Parameter, Severity, and Study Day
Total Bilirubin

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	29	97	1	3	-	-	-	-
	All Subjects	120	120	119	99	1	1	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	13	93	1	7	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	58	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	118	99	1	1	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	14	93	-	-	1	7	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	14	13	93	1	7	-	-	-	-
	All Subjects (18-55 years)	60	59	56	95	2	3	1	2	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	116	97	2	2	1	1	-	-
	25 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	59	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	119	99	1	1	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	14	93	-	-	1	7	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	All Subjects (18-55 years)	60	60	57	95	2	3	1	2	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	117	98	2	2	1	1	-	-

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 134: Laboratory Results by Parameter, Severity, and Study Day
Serum Lipase

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	Treatment Group	N	N*	n	%	n	%	n	%	n	%
Screening (Day -42 to -1)	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	14	93	-	-	1	7	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	59	98	-	-	1	2	-	-
	25 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	29	97	-	-	-	-	1	3
	All Subjects	120	120	117	98	1	1	1	1	1	1
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	14	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	2	7	-	-	1	3
	All Subjects	120	119	116	97	2	2	-	-	1	1
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	58	98	1	2	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	119	118	99	1	1	-	-	-	-
	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	-	-	1	7	-	-
	All Subjects (18-55 years)	60	60	58	97	1	2	1	2	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	117	98	2	2	1	1	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	-	-	-	-	1	7
	All Subjects (18-55 years)	60	60	58	97	1	2	-	-	1	2
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	9	90	-	-	-	-	1	10
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	2	7	-	-	1	3
	All Subjects	120	120	114	95	4	3	-	-	2	2

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 135: Shift Table of Laboratory Parameters – ALT

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	12	86	1	7	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	-	-	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	-	-	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	14	93	-	-	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	13	93	-	-	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	-	-	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 136: Shift Table of Laboratory Parameters – AST

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

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Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 137: Shift Table of Laboratory Parameters – Alkaline Phosphatase

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 138: Shift Table of Laboratory Parameters – Total Bilirubin

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	13	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	-	-	1	7	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

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Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	13	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

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Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 139: Shift Table of Laboratory Parameters – Creatinine

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 140: Shift Table of Laboratory Parameters – Serum Lipase

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	14	93	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	1	7	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	1	7	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	1	7	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	14	93	-	-	1	7	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	9	90	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

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Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	9	90	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	1	10
	Day 29 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	1	10	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	1	10	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 141: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Creatinine

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	0.903	0.171	0.880	0.58, 1.22
	50 µg (18-55 years)	15	0.853	0.083	0.830	0.73, 1.00
	100 µg (18-55 years)	15	0.872	0.169	0.830	0.64, 1.17
	250 µg (18-55 years)	15	0.835	0.146	0.840	0.58, 1.12
	All Subjects (18-55 years)	60	0.866	0.145	0.845	0.58, 1.22
	25 µg (56-70 years)	10	0.859	0.151	0.890	0.66, 1.12
	50 µg (56-70 years)	10	0.868	0.170	0.835	0.63, 1.08
	100 µg (56-70 years)	10	0.865	0.203	0.890	0.60, 1.13
	All Subjects (56-70 years)	30	0.864	0.170	0.860	0.60, 1.13
	25 µg (≥71 years)	10	0.892	0.197	0.830	0.58, 1.21
	50 µg (≥71 years)	10	0.842	0.153	0.865	0.60, 1.05
	100 µg (≥71 years)	10	0.797	0.156	0.805	0.55, 1.04
	All Subjects (≥71 years)	30	0.844	0.169	0.830	0.55, 1.21
	All Subjects	120	0.860	0.157	0.850	0.55, 1.22
Day 8	25 µg (18-55 years)	14	0.829	0.132	0.820	0.57, 1.00
	50 µg (18-55 years)	15	0.845	0.107	0.820	0.64, 1.10
	100 µg (18-55 years)	15	0.845	0.180	0.790	0.60, 1.20
	250 µg (18-55 years)	15	0.816	0.154	0.830	0.57, 1.16
	All Subjects (18-55 years)	59	0.834	0.143	0.810	0.57, 1.20
	25 µg (56-70 years)	10	0.859	0.164	0.870	0.64, 1.16
	50 µg (56-70 years)	10	0.901	0.156	0.890	0.63, 1.14
	100 µg (56-70 years)	10	0.903	0.170	0.915	0.56, 1.19
	All Subjects (56-70 years)	30	0.888	0.159	0.875	0.56, 1.19
	25 µg (≥71 years)	10	0.831	0.166	0.805	0.60, 1.07
	50 µg (≥71 years)	10	0.862	0.135	0.930	0.65, 1.00
	100 µg (≥71 years)	10	0.818	0.161	0.805	0.64, 1.09
	All Subjects (≥71 years)	30	0.837	0.151	0.855	0.60, 1.09
	All Subjects	119	0.848	0.149	0.840	0.56, 1.20
Day 8, Change from Baseline	25 µg (18-55 years)	14	-0.062	0.067	-0.060	-0.23, 0.01
	50 µg (18-55 years)	15	-0.007	0.085	-0.010	-0.16, 0.20
	100 µg (18-55 years)	15	-0.027	0.050	-0.010	-0.14, 0.03
	250 µg (18-55 years)	15	-0.019	0.057	-0.010	-0.12, 0.07
	All Subjects (18-55 years)	59	-0.028	0.067	-0.020	-0.23, 0.20
	25 µg (56-70 years)	10	-0.000	0.084	-0.015	-0.11, 0.19
	50 µg (56-70 years)	10	0.033	0.046	0.035	-0.03, 0.10
	100 µg (56-70 years)	10	0.038	0.103	0.025	-0.16, 0.22
	All Subjects (56-70 years)	30	0.024	0.080	0.015	-0.16, 0.22
	25 µg (≥71 years)	10	-0.061	0.062	-0.055	-0.19, 0.02
	50 µg (≥71 years)	10	0.020	0.065	0.055	-0.07, 0.10

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	0.021	0.033	0.005	-0.01, 0.09
	All Subjects (≥71 years)	30	-0.007	0.066	0.000	-0.19, 0.10
	All Subjects	119	-0.010	0.073	-0.010	-0.23, 0.22
Day 29	25 µg (18-55 years)	15	0.849	0.131	0.840	0.59, 1.00
	50 µg (18-55 years)	15	0.845	0.129	0.820	0.63, 1.08
	100 µg (18-55 years)	15	0.823	0.171	0.780	0.61, 1.14
	250 µg (18-55 years)	14	0.806	0.129	0.815	0.58, 1.09
	All Subjects (18-55 years)	59	0.831	0.139	0.820	0.58, 1.14
	25 µg (56-70 years)	10	0.870	0.148	0.875	0.64, 1.10
	50 µg (56-70 years)	10	0.919	0.161	0.880	0.69, 1.15
	100 µg (56-70 years)	10	0.844	0.172	0.865	0.56, 1.17
	All Subjects (56-70 years)	30	0.878	0.158	0.875	0.56, 1.17
	25 µg (≥71 years)	10	0.846	0.181	0.820	0.61, 1.15
	50 µg (≥71 years)	10	0.863	0.134	0.870	0.67, 1.05
	100 µg (≥71 years)	10	0.786	0.178	0.775	0.53, 1.07
	All Subjects (≥71 years)	30	0.832	0.164	0.815	0.53, 1.15
	All Subjects	119	0.843	0.150	0.820	0.53, 1.17
Day 29, Change from Baseline	25 µg (18-55 years)	15	-0.054	0.071	-0.040	-0.22, 0.05
	50 µg (18-55 years)	15	-0.007	0.122	-0.030	-0.17, 0.23
	100 µg (18-55 years)	15	-0.049	0.059	-0.040	-0.17, 0.02
	250 µg (18-55 years)	14	-0.047	0.046	-0.050	-0.12, 0.06
	All Subjects (18-55 years)	59	-0.039	0.080	-0.040	-0.22, 0.23
	25 µg (56-70 years)	10	0.011	0.081	-0.010	-0.11, 0.14
	50 µg (56-70 years)	10	0.051	0.031	0.060	-0.01, 0.09
	100 µg (56-70 years)	10	-0.021	0.083	-0.025	-0.21, 0.08
	All Subjects (56-70 years)	30	0.014	0.073	0.020	-0.21, 0.14
	25 µg (≥71 years)	10	-0.046	0.070	-0.050	-0.19, 0.04
	50 µg (≥71 years)	10	0.021	0.047	0.015	-0.04, 0.10
	100 µg (≥71 years)	10	-0.011	0.049	-0.020	-0.07, 0.10
	All Subjects (≥71 years)	30	-0.012	0.061	-0.015	-0.19, 0.10
	All Subjects	119	-0.019	0.077	-0.030	-0.22, 0.23
Day 36	25 µg (18-55 years)	15	0.873	0.161	0.900	0.53, 1.13
	50 µg (18-55 years)	15	0.833	0.078	0.820	0.67, 1.00
	100 µg (18-55 years)	15	0.839	0.174	0.770	0.58, 1.26
	250 µg (18-55 years)	15	0.801	0.123	0.800	0.60, 1.00
	All Subjects (18-55 years)	60	0.836	0.138	0.815	0.53, 1.26
	25 µg (56-70 years)	10	0.885	0.147	0.890	0.68, 1.12
	50 µg (56-70 years)	10	0.901	0.116	0.895	0.73, 1.08
	100 µg (56-70 years)	10	0.896	0.183	0.905	0.61, 1.25
	All Subjects (56-70 years)	30	0.894	0.146	0.895	0.61, 1.25
	25 µg (≥71 years)	10	0.862	0.161	0.925	0.62, 1.06

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	0.871	0.135	0.885	0.69, 1.13
	100 µg (≥71 years)	10	0.811	0.183	0.800	0.59, 1.09
	All Subjects (≥71 years)	30	0.848	0.158	0.885	0.59, 1.13
	All Subjects	120	0.854	0.146	0.850	0.53, 1.26
Day 36, Change from Baseline	25 µg (18-55 years)	15	-0.031	0.083	-0.030	-0.20, 0.10
	50 µg (18-55 years)	15	-0.020	0.067	0.000	-0.13, 0.07
	100 µg (18-55 years)	15	-0.033	0.078	-0.050	-0.18, 0.11
	250 µg (18-55 years)	15	-0.034	0.067	-0.020	-0.12, 0.08
	All Subjects (18-55 years)	60	-0.030	0.072	-0.030	-0.20, 0.11
	25 µg (56-70 years)	10	0.026	0.064	0.020	-0.08, 0.15
	50 µg (56-70 years)	10	0.033	0.078	0.050	-0.11, 0.13
	100 µg (56-70 years)	10	0.031	0.110	0.050	-0.20, 0.19
	All Subjects (56-70 years)	30	0.030	0.083	0.040	-0.20, 0.19
	25 µg (≥71 years)	10	-0.030	0.112	-0.025	-0.26, 0.11
	50 µg (≥71 years)	10	0.029	0.075	0.030	-0.11, 0.15
	100 µg (≥71 years)	10	0.014	0.053	0.025	-0.08, 0.09
	All Subjects (≥71 years)	30	0.004	0.085	0.015	-0.26, 0.15
	All Subjects	120	-0.006	0.082	0.000	-0.26, 0.19
N=Number of subjects in the Safety Population						

Table 142: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – ALT

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	20.0	13.2	14.0	9, 53
	50 µg (18-55 years)	15	15.9	5.8	16.0	7, 29
	100 µg (18-55 years)	15	19.1	9.1	15.0	9, 34
	250 µg (18-55 years)	15	16.9	12.5	13.0	7, 53
	All Subjects (18-55 years)	60	18.0	10.4	14.5	7, 53
	25 µg (56-70 years)	10	18.8	6.3	19.5	11, 30
	50 µg (56-70 years)	10	16.6	5.9	16.5	9, 24
	100 µg (56-70 years)	10	15.2	4.0	15.0	8, 23
	All Subjects (56-70 years)	30	16.9	5.5	15.5	8, 30
	25 µg (≥71 years)	10	20.4	6.4	19.0	13, 35
	50 µg (≥71 years)	10	18.3	3.0	17.5	14, 24
	100 µg (≥71 years)	10	18.7	9.4	17.0	10, 41
	All Subjects (≥71 years)	30	19.1	6.6	18.0	10, 41
	All Subjects	120	18.0	8.5	16.0	7, 53
Day 8	25 µg (18-55 years)	14	23.2	16.4	17.5	9, 66
	50 µg (18-55 years)	15	15.4	6.0	15.0	7, 31
	100 µg (18-55 years)	15	22.0	20.2	16.0	8, 88
	250 µg (18-55 years)	15	13.2	6.3	11.0	7, 27
	All Subjects (18-55 years)	59	18.4	14.0	15.0	7, 88
	25 µg (56-70 years)	10	16.5	5.9	16.5	9, 28
	50 µg (56-70 years)	10	16.3	6.7	15.0	7, 26
	100 µg (56-70 years)	10	15.1	3.8	14.5	9, 23
	All Subjects (56-70 years)	30	16.0	5.4	15.0	7, 28
	25 µg (≥71 years)	10	19.0	5.3	17.5	14, 33
	50 µg (≥71 years)	10	17.4	4.2	16.5	13, 28
	100 µg (≥71 years)	10	18.6	6.9	17.5	10, 35
	All Subjects (≥71 years)	30	18.3	5.4	17.0	10, 35
	All Subjects	119	17.8	10.6	16.0	7, 88
Day 8, Change from Baseline	25 µg (18-55 years)	14	3.1	8.5	1.5	-10, 28
	50 µg (18-55 years)	15	-0.5	2.9	-1.0	-6, 6
	100 µg (18-55 years)	15	2.9	15.4	-1.0	-8, 57
	250 µg (18-55 years)	15	-3.7	7.3	-1.0	-28, 2
	All Subjects (18-55 years)	59	0.4	9.8	-1.0	-28, 57
	25 µg (56-70 years)	10	-2.3	2.0	-2.0	-7, 0
	50 µg (56-70 years)	10	-0.3	1.3	0.0	-2, 2
	100 µg (56-70 years)	10	-0.1	1.0	0.0	-2, 1
	All Subjects (56-70 years)	30	-0.9	1.7	-1.0	-7, 2
	25 µg (≥71 years)	10	-1.4	2.5	-1.0	-7, 1
	50 µg (≥71 years)	10	-0.9	3.5	-1.0	-7, 6
	100 µg (≥71 years)	10	-0.1	3.6	-0.5	-6, 7

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	All Subjects (≥71 years)	30	-0.8	3.2	-1.0	-7, 7
	All Subjects	119	-0.2	7.1	-1.0	-28, 57
Day 29	25 µg (18-55 years)	15	18.1	9.7	16.0	8, 44
	50 µg (18-55 years)	15	16.3	7.0	17.0	6, 35
	100 µg (18-55 years)	15	19.9	13.9	14.0	7, 52
	250 µg (18-55 years)	14	14.4	8.5	11.0	6, 35
	All Subjects (18-55 years)	59	17.2	10.1	15.0	6, 52
	25 µg (56-70 years)	10	18.8	5.7	20.5	11, 26
	50 µg (56-70 years)	10	14.8	6.1	14.0	7, 24
	100 µg (56-70 years)	10	17.7	5.9	17.0	11, 32
	All Subjects (56-70 years)	30	17.1	5.9	17.0	7, 32
	25 µg (≥71 years)	10	19.1	9.3	16.5	14, 45
	50 µg (≥71 years)	10	17.0	4.1	15.5	13, 25
	100 µg (≥71 years)	10	18.3	8.4	16.0	10, 39
	All Subjects (≥71 years)	30	18.1	7.4	16.0	10, 45
	All Subjects	119	17.4	8.5	16.0	6, 52
Day 29, Change from Baseline	25 µg (18-55 years)	15	-1.9	5.5	-1.0	-14, 9
	50 µg (18-55 years)	15	0.4	3.3	1.0	-7, 6
	100 µg (18-55 years)	15	0.7	6.3	-1.0	-7, 18
	250 µg (18-55 years)	14	-3.1	6.6	-1.0	-25, 1
	All Subjects (18-55 years)	59	-0.9	5.6	-1.0	-25, 18
	25 µg (56-70 years)	10	0.0	2.8	0.0	-4, 6
	50 µg (56-70 years)	10	-1.8	2.1	-1.0	-6, 0
	100 µg (56-70 years)	10	2.5	3.4	2.5	-2, 9
	All Subjects (56-70 years)	30	0.2	3.3	0.0	-6, 9
	25 µg (≥71 years)	10	-1.3	4.8	-1.5	-8, 10
	50 µg (≥71 years)	10	-1.3	2.5	-1.5	-6, 2
	100 µg (≥71 years)	10	-0.4	2.4	-0.5	-5, 3
	All Subjects (≥71 years)	30	-1.0	3.3	-1.0	-8, 10
	All Subjects	119	-0.7	4.6	-1.0	-25, 18
Day 36	25 µg (18-55 years)	15	20.9	14.0	16.0	7, 46
	50 µg (18-55 years)	15	15.9	7.2	15.0	7, 37
	100 µg (18-55 years)	15	18.1	8.2	16.0	10, 37
	250 µg (18-55 years)	15	15.4	8.3	13.0	9, 34
	All Subjects (18-55 years)	60	17.6	9.8	15.0	7, 46
	25 µg (56-70 years)	10	17.9	6.7	16.5	11, 28
	50 µg (56-70 years)	10	15.2	7.0	13.0	7, 31
	100 µg (56-70 years)	10	18.2	7.4	17.5	10, 37
	All Subjects (56-70 years)	30	17.1	6.9	15.5	7, 37
	25 µg (≥71 years)	10	18.2	5.3	16.0	13, 32
	50 µg (≥71 years)	10	15.8	3.6	14.5	12, 22

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	18.2	7.3	16.0	10, 34
	All Subjects (≥71 years)	30	17.4	5.5	16.0	10, 34
	All Subjects	120	17.4	8.2	15.0	7, 46
Day 36, Change from Baseline	25 µg (18-55 years)	15	0.9	9.4	-1.0	-9, 31
	50 µg (18-55 years)	15	0.1	3.2	0.0	-5, 8
	100 µg (18-55 years)	15	-1.0	4.3	0.0	-10, 5
	250 µg (18-55 years)	15	-1.5	8.6	0.0	-29, 11
	All Subjects (18-55 years)	60	-0.4	6.8	0.0	-29, 31
	25 µg (56-70 years)	10	-0.9	3.2	-0.5	-7, 4
	50 µg (56-70 years)	10	-1.4	3.9	-2.0	-7, 7
	100 µg (56-70 years)	10	3.0	4.4	3.0	-2, 14
	All Subjects (56-70 years)	30	0.2	4.2	0.0	-7, 14
	25 µg (≥71 years)	10	-2.2	3.2	-2.0	-7, 3
	50 µg (≥71 years)	10	-2.5	2.5	-3.0	-7, 1
	100 µg (≥71 years)	10	-0.5	2.8	-0.5	-7, 3
	All Subjects (≥71 years)	30	-1.7	2.9	-1.5	-7, 3
	All Subjects	120	-0.6	5.5	-1.0	-29, 31
N=Number of subjects in the Safety Population						

Table 143: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – AST

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	19.4	4.3	20.0	14, 31
	50 µg (18-55 years)	15	17.2	5.6	16.0	11, 33
	100 µg (18-55 years)	15	17.7	4.9	17.0	11, 29
	250 µg (18-55 years)	15	17.6	6.7	15.0	11, 38
	All Subjects (18-55 years)	60	18.0	5.4	17.0	11, 38
	25 µg (56-70 years)	10	20.5	4.1	20.5	13, 25
	50 µg (56-70 years)	10	21.7	4.3	22.5	17, 29
	100 µg (56-70 years)	10	20.4	3.9	20.0	15, 27
	All Subjects (56-70 years)	30	20.9	4.0	21.5	13, 29
	25 µg (≥71 years)	10	20.2	3.0	19.5	16, 25
	50 µg (≥71 years)	10	21.4	5.4	19.0	16, 35
	100 µg (≥71 years)	10	21.3	5.1	21.5	15, 30
	All Subjects (≥71 years)	30	21.0	4.5	19.5	15, 35
	All Subjects	120	19.4	5.0	19.0	11, 38
Day 8	25 µg (18-55 years)	14	19.6	6.1	18.0	11, 31
	50 µg (18-55 years)	15	17.4	5.1	16.0	11, 29
	100 µg (18-55 years)	15	18.6	7.2	17.0	11, 41
	250 µg (18-55 years)	15	16.8	3.5	16.0	12, 24
	All Subjects (18-55 years)	59	18.1	5.6	17.0	11, 41
	25 µg (56-70 years)	10	18.6	4.9	16.0	13, 26
	50 µg (56-70 years)	10	21.5	5.9	22.0	14, 34
	100 µg (56-70 years)	10	18.7	3.8	20.0	12, 24
	All Subjects (56-70 years)	30	19.6	4.9	20.0	12, 34
	25 µg (≥71 years)	10	19.6	3.6	18.5	15, 28
	50 µg (≥71 years)	10	20.8	5.6	19.0	16, 35
	100 µg (≥71 years)	10	21.6	4.4	21.0	16, 29
	All Subjects (≥71 years)	30	20.7	4.5	19.0	15, 35
	All Subjects	119	19.1	5.3	18.0	11, 41
Day 8, Change from Baseline	25 µg (18-55 years)	14	1.1	5.2	0.5	-9, 11
	50 µg (18-55 years)	15	0.2	5.2	1.0	-14, 9
	100 µg (18-55 years)	15	0.9	3.9	0.0	-4, 12
	250 µg (18-55 years)	15	-0.8	4.4	0.0	-14, 4
	All Subjects (18-55 years)	59	0.3	4.6	0.0	-14, 12
	25 µg (56-70 years)	10	-1.9	4.1	-1.5	-9, 5
	50 µg (56-70 years)	10	-0.2	2.3	-0.5	-3, 5
	100 µg (56-70 years)	10	-1.7	1.7	-2.0	-4, 1
	All Subjects (56-70 years)	30	-1.3	2.9	-1.0	-9, 5
	25 µg (≥71 years)	10	-0.6	2.2	-0.5	-4, 3
	50 µg (≥71 years)	10	-0.6	3.5	-0.5	-8, 4
	100 µg (≥71 years)	10	0.3	2.1	-0.5	-2, 4

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	All Subjects (≥71 years)	30	-0.3	2.6	-0.5	-8, 4
	All Subjects	119	-0.2	3.8	0.0	-14, 12
Day 29	25 µg (18-55 years)	15	17.5	3.9	18.0	12, 24
	50 µg (18-55 years)	15	17.9	5.3	18.0	10, 32
	100 µg (18-55 years)	15	17.3	4.8	17.0	11, 27
	250 µg (18-55 years)	14	16.9	3.9	16.0	12, 24
	All Subjects (18-55 years)	59	17.4	4.4	17.0	10, 32
	25 µg (56-70 years)	10	18.7	4.2	18.5	13, 25
	50 µg (56-70 years)	10	21.0	5.8	19.5	14, 30
	100 µg (56-70 years)	10	24.4	11.3	21.5	14, 54
	All Subjects (56-70 years)	30	21.4	7.8	20.5	13, 54
	25 µg (≥71 years)	10	19.2	4.7	18.5	15, 31
	50 µg (≥71 years)	10	21.2	4.2	19.5	17, 31
	100 µg (≥71 years)	10	19.7	4.7	19.5	14, 28
	All Subjects (≥71 years)	30	20.0	4.5	19.0	14, 31
	All Subjects	119	19.1	5.7	18.0	10, 54
Day 29, Change from Baseline	25 µg (18-55 years)	15	-1.9	4.0	-1.0	-8, 6
	50 µg (18-55 years)	15	0.7	5.0	1.0	-13, 8
	100 µg (18-55 years)	15	-0.3	3.7	0.0	-9, 6
	250 µg (18-55 years)	14	-0.7	4.4	1.0	-14, 4
	All Subjects (18-55 years)	59	-0.5	4.3	0.0	-14, 8
	25 µg (56-70 years)	10	-1.8	3.3	-1.0	-8, 3
	50 µg (56-70 years)	10	-0.7	3.4	-0.5	-6, 7
	100 µg (56-70 years)	10	4.0	8.4	1.0	-2, 27
	All Subjects (56-70 years)	30	0.5	6.0	0.0	-8, 27
	25 µg (≥71 years)	10	-1.0	2.9	-1.0	-5, 6
	50 µg (≥71 years)	10	-0.2	1.9	0.0	-4, 2
	100 µg (≥71 years)	10	-1.6	2.7	-1.0	-7, 3
	All Subjects (≥71 years)	30	-0.9	2.5	-1.0	-7, 6
	All Subjects	119	-0.4	4.4	0.0	-14, 27
Day 36	25 µg (18-55 years)	15	19.3	8.4	17.0	10, 45
	50 µg (18-55 years)	15	16.3	5.7	16.0	9, 33
	100 µg (18-55 years)	15	17.5	4.0	17.0	12, 26
	250 µg (18-55 years)	15	16.3	4.3	15.0	8, 25
	All Subjects (18-55 years)	60	17.4	5.9	16.0	8, 45
	25 µg (56-70 years)	10	19.0	6.2	16.0	13, 29
	50 µg (56-70 years)	10	19.7	4.7	20.0	13, 26
	100 µg (56-70 years)	10	20.2	4.7	22.0	13, 27
	All Subjects (56-70 years)	30	19.6	5.1	20.0	13, 29
	25 µg (≥71 years)	10	19.5	3.5	20.0	15, 27
	50 µg (≥71 years)	10	21.7	7.9	18.5	16, 42

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	20.0	4.6	19.5	15, 28
	All Subjects (≥71 years)	30	20.4	5.5	19.5	15, 42
	All Subjects	120	18.7	5.7	17.5	8, 45
Day 36, Change from Baseline	25 µg (18-55 years)	15	-0.1	8.1	-1.0	-10, 27
	50 µg (18-55 years)	15	-0.9	5.3	-1.0	-15, 9
	100 µg (18-55 years)	15	-0.1	3.9	1.0	-9, 5
	250 µg (18-55 years)	15	-1.3	4.9	0.0	-17, 6
	All Subjects (18-55 years)	60	-0.6	5.7	-1.0	-17, 27
	25 µg (56-70 years)	10	-1.5	4.9	-2.0	-10, 5
	50 µg (56-70 years)	10	-2.0	2.5	-3.0	-5, 3
	100 µg (56-70 years)	10	-0.2	3.3	-0.5	-4, 5
	All Subjects (56-70 years)	30	-1.2	3.6	-2.0	-10, 5
	25 µg (≥71 years)	10	-0.7	2.9	-0.5	-6, 3
	50 µg (≥71 years)	10	0.3	2.9	-0.5	-3, 7
	100 µg (≥71 years)	10	-1.3	2.8	-1.0	-8, 1
	All Subjects (≥71 years)	30	-0.6	2.8	-0.5	-8, 7
	All Subjects	120	-0.8	4.6	-1.0	-17, 27
N=Number of subjects in the Safety Population						

Table 144: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Alkaline Phosphatase

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	58.4	13.6	53.0	45, 84
	50 µg (18-55 years)	15	54.8	14.6	54.0	37, 87
	100 µg (18-55 years)	15	62.4	15.3	63.0	42, 91
	250 µg (18-55 years)	15	56.9	20.5	53.0	40, 122
	All Subjects (18-55 years)	60	58.1	16.1	54.0	37, 122
	25 µg (56-70 years)	10	68.5	15.1	63.5	53, 103
	50 µg (56-70 years)	10	67.7	10.5	66.0	55, 90
	100 µg (56-70 years)	10	61.9	14.5	63.0	39, 82
	All Subjects (56-70 years)	30	66.0	13.4	65.0	39, 103
	25 µg (≥71 years)	10	63.9	14.6	62.5	45, 87
	50 µg (≥71 years)	10	69.9	18.4	69.5	48, 110
	100 µg (≥71 years)	10	58.1	9.6	57.5	43, 71
	All Subjects (≥71 years)	30	64.0	15.0	62.0	43, 110
	All Subjects	120	61.6	15.4	60.0	37, 122
Day 8	25 µg (18-55 years)	14	52.6	11.7	50.5	34, 71
	50 µg (18-55 years)	15	55.9	14.7	53.0	39, 89
	100 µg (18-55 years)	15	59.0	15.2	55.0	36, 90
	250 µg (18-55 years)	15	55.3	15.9	51.0	39, 105
	All Subjects (18-55 years)	59	55.7	14.3	53.0	34, 105
	25 µg (56-70 years)	10	66.6	17.2	63.0	49, 104
	50 µg (56-70 years)	10	65.3	8.3	65.5	55, 80
	100 µg (56-70 years)	10	63.5	15.1	63.0	37, 83
	All Subjects (56-70 years)	30	65.1	13.6	64.5	37, 104
	25 µg (≥71 years)	10	61.3	16.0	58.5	40, 90
	50 µg (≥71 years)	10	68.7	18.6	63.5	44, 100
	100 µg (≥71 years)	10	54.8	8.4	53.5	42, 71
	All Subjects (≥71 years)	30	61.6	15.6	58.5	40, 100
	All Subjects	119	59.6	14.9	56.0	34, 105
Day 8, Change from Baseline	25 µg (18-55 years)	14	-6.7	7.1	-6.0	-18, 8
	50 µg (18-55 years)	15	1.1	4.7	2.0	-8, 10
	100 µg (18-55 years)	15	-3.4	10.5	-1.0	-32, 14
	250 µg (18-55 years)	15	-1.6	6.8	2.0	-17, 6
	All Subjects (18-55 years)	59	-2.6	7.9	-1.0	-32, 14
	25 µg (56-70 years)	10	-1.9	4.5	-2.0	-8, 4
	50 µg (56-70 years)	10	-2.4	5.2	-1.5	-15, 3
	100 µg (56-70 years)	10	1.6	5.7	0.0	-4, 15
	All Subjects (56-70 years)	30	-0.9	5.3	-1.0	-15, 15
	25 µg (≥71 years)	10	-2.6	5.5	-2.0	-12, 5
	50 µg (≥71 years)	10	-1.2	6.3	-1.5	-10, 10

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	-3.3	5.1	-1.5	-13, 4
	All Subjects (≥71 years)	30	-2.4	5.5	-1.5	-13, 10
	All Subjects	119	-2.1	6.8	-1.0	-32, 15
Day 29	25 µg (18-55 years)	15	54.3	13.4	50.0	32, 78
	50 µg (18-55 years)	15	52.9	11.8	47.0	38, 77
	100 µg (18-55 years)	15	55.2	14.5	55.0	32, 77
	250 µg (18-55 years)	14	56.4	18.4	50.5	36, 106
	All Subjects (18-55 years)	59	54.6	14.3	50.0	32, 106
	25 µg (56-70 years)	10	67.9	16.8	64.0	47, 102
	50 µg (56-70 years)	10	66.3	9.6	66.5	52, 82
	100 µg (56-70 years)	10	61.9	13.4	64.5	42, 83
	All Subjects (56-70 years)	30	65.4	13.4	65.0	42, 102
	25 µg (≥71 years)	10	68.7	27.2	63.0	44, 134
	50 µg (≥71 years)	10	68.4	17.2	69.0	47, 98
	100 µg (≥71 years)	10	58.1	12.2	55.5	41, 86
	All Subjects (≥71 years)	30	65.1	19.8	59.0	41, 134
	All Subjects	119	60.0	16.4	57.0	32, 134
Day 29, Change from Baseline	25 µg (18-55 years)	15	-4.1	9.0	-3.0	-21, 10
	50 µg (18-55 years)	15	-1.9	6.0	-3.0	-10, 9
	100 µg (18-55 years)	15	-7.2	7.6	-8.0	-18, 5
	250 µg (18-55 years)	14	-0.4	5.9	1.5	-16, 5
	All Subjects (18-55 years)	59	-3.5	7.5	-3.0	-21, 10
	25 µg (56-70 years)	10	-0.6	4.7	-0.5	-8, 6
	50 µg (56-70 years)	10	-1.4	3.6	-1.0	-10, 2
	100 µg (56-70 years)	10	0.0	7.1	1.5	-15, 12
	All Subjects (56-70 years)	30	-0.7	5.2	0.0	-15, 12
	25 µg (≥71 years)	10	4.8	16.2	0.5	-8, 47
	50 µg (≥71 years)	10	-1.5	5.7	-2.0	-12, 11
	100 µg (≥71 years)	10	0.0	7.4	0.0	-12, 16
	All Subjects (≥71 years)	30	1.1	10.8	-1.0	-12, 47
	All Subjects	119	-1.6	8.2	-1.0	-21, 47
Day 36	25 µg (18-55 years)	15	58.0	14.8	57.0	33, 78
	50 µg (18-55 years)	15	53.7	12.0	49.0	37, 77
	100 µg (18-55 years)	15	58.3	13.2	55.0	39, 81
	250 µg (18-55 years)	15	54.0	13.6	51.0	35, 93
	All Subjects (18-55 years)	60	56.0	13.2	53.5	33, 93
	25 µg (56-70 years)	10	69.7	17.2	66.5	51, 104
	50 µg (56-70 years)	10	66.8	8.3	65.0	57, 81
	100 µg (56-70 years)	10	64.8	15.3	64.5	41, 88
	All Subjects (56-70 years)	30	67.1	13.8	65.0	41, 104
	25 µg (≥71 years)	10	65.7	21.2	61.5	46, 120

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	67.5	16.4	67.5	48, 99
	100 µg (≥71 years)	10	62.1	12.7	60.5	47, 92
	All Subjects (≥71 years)	30	65.1	16.7	61.0	46, 120
	All Subjects	120	61.0	15.1	58.5	33, 120
Day 36, Change from Baseline	25 µg (18-55 years)	15	-0.4	8.4	-1.0	-15, 15
	50 µg (18-55 years)	15	-1.1	7.0	0.0	-19, 9
	100 µg (18-55 years)	15	-4.1	8.6	-3.0	-27, 8
	250 µg (18-55 years)	15	-2.9	9.2	0.0	-29, 6
	All Subjects (18-55 years)	60	-2.1	8.3	-1.0	-29, 15
	25 µg (56-70 years)	10	1.2	6.2	1.0	-8, 11
	50 µg (56-70 years)	10	-0.9	5.7	-2.5	-9, 8
	100 µg (56-70 years)	10	2.9	6.5	5.5	-7, 12
	All Subjects (56-70 years)	30	1.1	6.1	1.0	-9, 12
	25 µg (≥71 years)	10	1.8	12.3	-2.0	-11, 33
	50 µg (≥71 years)	10	-2.4	4.5	-2.0	-11, 4
	100 µg (≥71 years)	10	4.0	8.4	2.5	-5, 22
	All Subjects (≥71 years)	30	1.1	9.1	-2.0	-11, 33
	All Subjects	120	-0.5	8.1	-1.0	-29, 33
N=Number of subjects in the Safety Population						

Table 145: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Total Bilirubin

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	0.61	0.30	0.50	0.3, 1.3
	50 µg (18-55 years)	15	0.73	0.30	0.70	0.3, 1.3
	100 µg (18-55 years)	15	0.57	0.27	0.50	0.3, 1.3
	250 µg (18-55 years)	15	0.56	0.27	0.50	0.2, 1.2
	All Subjects (18-55 years)	60	0.62	0.29	0.55	0.2, 1.3
	25 µg (56-70 years)	10	0.76	0.28	0.75	0.3, 1.2
	50 µg (56-70 years)	10	0.57	0.26	0.50	0.2, 1.1
	100 µg (56-70 years)	10	0.51	0.17	0.50	0.3, 0.8
	All Subjects (56-70 years)	30	0.61	0.26	0.55	0.2, 1.2
	25 µg (≥71 years)	10	0.61	0.11	0.60	0.5, 0.8
	50 µg (≥71 years)	10	0.57	0.17	0.50	0.4, 0.9
	100 µg (≥71 years)	10	0.64	0.30	0.60	0.4, 1.4
	All Subjects (≥71 years)	30	0.61	0.20	0.55	0.4, 1.4
	All Subjects	120	0.61	0.26	0.55	0.2, 1.4
Day 8	25 µg (18-55 years)	14	0.71	0.34	0.60	0.4, 1.6
	50 µg (18-55 years)	15	0.62	0.22	0.50	0.4, 1.0
	100 µg (18-55 years)	15	0.56	0.27	0.50	0.2, 1.2
	250 µg (18-55 years)	15	0.64	0.23	0.60	0.3, 1.1
	All Subjects (18-55 years)	59	0.63	0.27	0.60	0.2, 1.6
	25 µg (56-70 years)	10	0.69	0.17	0.60	0.5, 1.0
	50 µg (56-70 years)	10	0.57	0.28	0.50	0.2, 1.0
	100 µg (56-70 years)	10	0.50	0.20	0.50	0.3, 1.0
	All Subjects (56-70 years)	30	0.59	0.23	0.50	0.2, 1.0
	25 µg (≥71 years)	10	0.63	0.13	0.60	0.4, 0.9
	50 µg (≥71 years)	10	0.55	0.24	0.50	0.3, 1.0
	100 µg (≥71 years)	10	0.55	0.20	0.50	0.3, 0.9
	All Subjects (≥71 years)	30	0.58	0.19	0.60	0.3, 1.0
	All Subjects	119	0.61	0.24	0.60	0.2, 1.6
Day 8, Change from Baseline	25 µg (18-55 years)	14	0.11	0.18	0.10	-0.2, 0.4
	50 µg (18-55 years)	15	-0.11	0.16	-0.10	-0.5, 0.1
	100 µg (18-55 years)	15	-0.01	0.18	0.00	-0.3, 0.4
	250 µg (18-55 years)	15	0.08	0.20	0.10	-0.3, 0.4
	All Subjects (18-55 years)	59	0.02	0.19	0.00	-0.5, 0.4
	25 µg (56-70 years)	10	-0.07	0.25	-0.10	-0.5, 0.3
	50 µg (56-70 years)	10	-0.00	0.12	0.00	-0.2, 0.2
	100 µg (56-70 years)	10	-0.01	0.17	0.00	-0.3, 0.3
	All Subjects (56-70 years)	30	-0.03	0.18	0.00	-0.5, 0.3
	25 µg (≥71 years)	10	0.02	0.13	0.00	-0.1, 0.3
	50 µg (≥71 years)	10	-0.02	0.14	0.00	-0.2, 0.2

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	-0.09	0.22	-0.05	-0.6, 0.2
	All Subjects (≥71 years)	30	-0.03	0.17	0.00	-0.6, 0.3
	All Subjects	119	-0.01	0.18	0.00	-0.6, 0.4
Day 29	25 µg (18-55 years)	15	0.75	0.42	0.60	0.4, 2.1
	50 µg (18-55 years)	15	0.71	0.22	0.70	0.4, 1.1
	100 µg (18-55 years)	15	0.54	0.29	0.50	0.3, 1.4
	250 µg (18-55 years)	14	0.59	0.29	0.50	0.3, 1.5
	All Subjects (18-55 years)	59	0.65	0.32	0.60	0.3, 2.1
	25 µg (56-70 years)	10	0.60	0.25	0.50	0.3, 1.2
	50 µg (56-70 years)	10	0.54	0.26	0.45	0.2, 0.9
	100 µg (56-70 years)	10	0.53	0.27	0.45	0.3, 1.2
	All Subjects (56-70 years)	30	0.56	0.25	0.50	0.2, 1.2
	25 µg (≥71 years)	10	0.72	0.23	0.60	0.6, 1.3
	50 µg (≥71 years)	10	0.61	0.26	0.55	0.3, 1.1
	100 µg (≥71 years)	10	0.63	0.22	0.55	0.4, 1.1
	All Subjects (≥71 years)	30	0.65	0.23	0.60	0.3, 1.3
	All Subjects	119	0.63	0.28	0.60	0.2, 2.1
Day 29, Change from Baseline	25 µg (18-55 years)	15	0.14	0.25	0.10	-0.1, 0.8
	50 µg (18-55 years)	15	-0.03	0.27	0.10	-0.5, 0.4
	100 µg (18-55 years)	15	-0.03	0.11	0.00	-0.3, 0.1
	250 µg (18-55 years)	14	-0.00	0.18	0.00	-0.3, 0.3
	All Subjects (18-55 years)	59	0.02	0.22	0.00	-0.5, 0.8
	25 µg (56-70 years)	10	-0.16	0.27	-0.15	-0.7, 0.3
	50 µg (56-70 years)	10	-0.03	0.11	0.00	-0.2, 0.2
	100 µg (56-70 years)	10	0.02	0.21	0.00	-0.2, 0.5
	All Subjects (56-70 years)	30	-0.06	0.21	0.00	-0.7, 0.5
	25 µg (≥71 years)	10	0.11	0.26	0.10	-0.2, 0.7
	50 µg (≥71 years)	10	0.04	0.13	0.00	-0.2, 0.2
	100 µg (≥71 years)	10	-0.01	0.16	0.05	-0.3, 0.2
	All Subjects (≥71 years)	30	0.05	0.19	0.05	-0.3, 0.7
	All Subjects	119	0.01	0.21	0.00	-0.7, 0.8
Day 36	25 µg (18-55 years)	15	0.71	0.35	0.60	0.4, 1.8
	50 µg (18-55 years)	15	0.59	0.20	0.50	0.4, 1.1
	100 µg (18-55 years)	15	0.55	0.27	0.50	0.3, 1.3
	250 µg (18-55 years)	15	0.55	0.24	0.50	0.3, 1.1
	All Subjects (18-55 years)	60	0.60	0.27	0.50	0.3, 1.8
	25 µg (56-70 years)	10	0.62	0.27	0.55	0.3, 1.2
	50 µg (56-70 years)	10	0.52	0.21	0.50	0.1, 0.9
	100 µg (56-70 years)	10	0.47	0.15	0.40	0.3, 0.7
	All Subjects (56-70 years)	30	0.54	0.22	0.50	0.1, 1.2
	25 µg (≥71 years)	10	0.63	0.17	0.60	0.4, 0.9

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	0.67	0.32	0.50	0.4, 1.3
	100 µg (≥71 years)	10	0.53	0.12	0.50	0.4, 0.7
	All Subjects (≥71 years)	30	0.61	0.22	0.55	0.4, 1.3
	All Subjects	120	0.59	0.25	0.50	0.1, 1.8
Day 36, Change from Baseline	25 µg (18-55 years)	15	0.10	0.20	0.10	-0.2, 0.5
	50 µg (18-55 years)	15	-0.15	0.21	-0.10	-0.6, 0.1
	100 µg (18-55 years)	15	-0.02	0.12	0.00	-0.2, 0.2
	250 µg (18-55 years)	15	-0.01	0.19	0.00	-0.3, 0.5
	All Subjects (18-55 years)	60	-0.02	0.20	0.00	-0.6, 0.5
	25 µg (56-70 years)	10	-0.14	0.26	-0.10	-0.7, 0.3
	50 µg (56-70 years)	10	-0.05	0.18	0.00	-0.4, 0.1
	100 µg (56-70 years)	10	-0.04	0.08	-0.10	-0.1, 0.1
	All Subjects (56-70 years)	30	-0.08	0.19	-0.10	-0.7, 0.3
	25 µg (≥71 years)	10	0.02	0.14	0.00	-0.2, 0.3
	50 µg (≥71 years)	10	0.10	0.18	0.05	-0.1, 0.5
	100 µg (≥71 years)	10	-0.11	0.22	0.00	-0.7, 0.0
	All Subjects (≥71 years)	30	0.00	0.20	0.00	-0.7, 0.5
	All Subjects	120	-0.03	0.20	0.00	-0.7, 0.5
N=Number of subjects in the Safety Population						

Table 146: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Serum Lipase

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	23.48	11.25	19.00	11.0, 54.0
	50 µg (18-55 years)	15	28.13	25.59	23.00	12.0, 118.0
	100 µg (18-55 years)	15	25.07	12.67	24.00	10.0, 54.0
	250 µg (18-55 years)	15	26.60	16.20	21.00	10.0, 62.0
	All Subjects (18-55 years)	60	25.82	17.00	21.00	10.0, 118.0
	25 µg (56-70 years)	10	29.90	16.54	26.00	9.0, 67.0
	50 µg (56-70 years)	10	25.60	10.43	20.50	15.0, 43.0
	100 µg (56-70 years)	10	37.80	13.55	38.00	19.0, 56.0
	All Subjects (56-70 years)	30	31.10	14.21	29.00	9.0, 67.0
	25 µg (≥71 years)	10	40.40	13.59	37.00	17.0, 62.0
	50 µg (≥71 years)	10	50.60	46.92	32.00	27.0, 181.0
	100 µg (≥71 years)	10	26.60	5.74	27.00	18.0, 34.0
	All Subjects (≥71 years)	30	39.20	29.17	32.00	17.0, 181.0
	All Subjects	120	30.49	20.74	27.00	9.0, 181.0
Day 8	25 µg (18-55 years)	14	20.64	8.94	18.00	8.0, 46.0
	50 µg (18-55 years)	15	26.80	15.09	22.00	12.0, 60.0
	100 µg (18-55 years)	15	25.93	11.90	24.00	12.0, 53.0
	250 µg (18-55 years)	15	24.07	13.36	19.00	9.0, 55.0
	All Subjects (18-55 years)	59	24.42	12.48	21.00	8.0, 60.0
	25 µg (56-70 years)	10	27.90	13.50	23.50	12.0, 54.0
	50 µg (56-70 years)	10	27.10	11.95	25.50	14.0, 52.0
	100 µg (56-70 years)	10	37.00	16.25	36.50	11.0, 65.0
	All Subjects (56-70 years)	30	30.67	14.27	28.50	11.0, 65.0
	25 µg (≥71 years)	10	39.10	12.56	39.00	22.0, 67.0
	50 µg (≥71 years)	10	66.40	95.46	33.50	23.0, 336.0
	100 µg (≥71 years)	10	29.40	14.25	26.50	18.0, 67.0
	All Subjects (≥71 years)	30	44.97	56.51	32.50	18.0, 336.0
	All Subjects	119	31.18	31.35	24.00	8.0, 336.0
Day 8, Change from Baseline	25 µg (18-55 years)	14	-1.94	4.86	-1.50	-12.0, 7.0
	50 µg (18-55 years)	15	-1.33	22.72	0.00	-74.0, 35.0
	100 µg (18-55 years)	15	0.87	6.25	0.00	-13.0, 13.0
	250 µg (18-55 years)	15	-2.53	7.08	-1.00	-21.0, 8.0
	All Subjects (18-55 years)	59	-1.22	12.37	-1.00	-74.0, 35.0
	25 µg (56-70 years)	10	-2.00	8.31	1.50	-18.0, 6.0
	50 µg (56-70 years)	10	1.50	4.84	1.50	-8.0, 9.0
	100 µg (56-70 years)	10	-0.80	7.35	0.50	-13.0, 9.0
	All Subjects (56-70 years)	30	-0.43	6.90	1.00	-18.0, 9.0
	25 µg (≥71 years)	10	-1.30	6.11	-1.50	-14.0, 6.0
	50 µg (≥71 years)	10	15.80	49.91	1.50	-25.0, 155.0

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	2.80	15.46	-1.50	-12.0, 43.0
	All Subjects (≥71 years)	30	5.77	30.23	1.00	-25.0, 155.0
	All Subjects	119	0.74	17.90	0.00	-74.0, 155.0
Day 29	25 µg (18-55 years)	15	22.40	10.83	17.00	10.0, 50.0
	50 µg (18-55 years)	15	25.00	14.80	21.00	10.0, 57.0
	100 µg (18-55 years)	15	32.27	18.69	27.00	11.0, 78.0
	250 µg (18-55 years)	14	27.14	13.89	23.00	10.0, 58.0
	All Subjects (18-55 years)	59	26.69	14.91	22.00	10.0, 78.0
	25 µg (56-70 years)	10	32.20	13.58	31.00	16.0, 62.0
	50 µg (56-70 years)	10	26.70	12.49	22.00	12.0, 48.0
	100 µg (56-70 years)	10	36.80	14.64	39.00	14.0, 62.0
	All Subjects (56-70 years)	30	31.90	13.78	30.00	12.0, 62.0
	25 µg (≥71 years)	10	37.90	11.83	34.50	21.0, 55.0
	50 µg (≥71 years)	10	36.70	10.24	35.00	26.0, 48.0
	100 µg (≥71 years)	10	29.30	7.92	29.00	19.0, 46.0
	All Subjects (≥71 years)	30	34.63	10.51	31.50	19.0, 55.0
	All Subjects	119	30.01	13.96	27.00	10.0, 78.0
Day 29, Change from Baseline	25 µg (18-55 years)	15	-1.08	3.72	-1.00	-9.0, 5.0
	50 µg (18-55 years)	15	-3.13	17.67	-1.00	-61.0, 18.0
	100 µg (18-55 years)	15	7.20	10.15	5.00	-8.0, 31.0
	250 µg (18-55 years)	14	-0.14	7.36	0.50	-23.0, 9.0
	All Subjects (18-55 years)	59	0.73	11.46	0.00	-61.0, 31.0
	25 µg (56-70 years)	10	2.30	7.17	1.50	-5.0, 14.0
	50 µg (56-70 years)	10	1.10	3.93	1.50	-6.0, 8.0
	100 µg (56-70 years)	10	-1.00	8.38	0.00	-13.0, 12.0
	All Subjects (56-70 years)	30	0.80	6.67	1.50	-13.0, 14.0
	25 µg (≥71 years)	10	-2.50	4.97	-2.50	-10.0, 4.0
	50 µg (≥71 years)	10	-13.90	43.60	-1.00	-133.0, 16.0
	100 µg (≥71 years)	10	2.70	9.20	3.50	-12.0, 22.0
	All Subjects (≥71 years)	30	-4.57	25.95	-1.00	-133.0, 22.0
	All Subjects	119	-0.59	15.70	0.00	-133.0, 31.0
Day 36	25 µg (18-55 years)	15	21.93	9.75	19.00	10.0, 48.0
	50 µg (18-55 years)	15	23.80	10.84	21.00	13.0, 50.0
	100 µg (18-55 years)	15	28.07	15.25	24.00	11.0, 70.0
	250 µg (18-55 years)	15	31.27	27.00	24.00	10.0, 112.0
	All Subjects (18-55 years)	60	26.27	17.09	22.00	10.0, 112.0
	25 µg (56-70 years)	10	28.90	9.21	28.00	15.0, 43.0
	50 µg (56-70 years)	10	31.10	10.26	29.00	18.0, 47.0
	100 µg (56-70 years)	10	38.90	17.22	36.50	16.0, 72.0
	All Subjects (56-70 years)	30	32.97	13.04	31.00	15.0, 72.0
	25 µg (≥71 years)	10	38.60	11.54	40.50	23.0, 55.0

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	36.90	13.16	32.00	22.0, 62.0
	100 µg (≥71 years)	10	31.00	6.78	30.00	23.0, 46.0
	All Subjects (≥71 years)	30	35.50	10.97	30.50	22.0, 62.0
	All Subjects	120	30.25	15.24	28.00	10.0, 112.0
Day 36, Change from Baseline	25 µg (18-55 years)	15	-1.55	6.29	-1.00	-13.0, 13.0
	50 µg (18-55 years)	15	-4.33	18.05	-1.00	-68.0, 7.0
	100 µg (18-55 years)	15	3.00	7.70	2.00	-10.0, 16.0
	250 µg (18-55 years)	15	4.67	13.75	1.00	-12.0, 50.0
	All Subjects (18-55 years)	60	0.45	12.59	0.00	-68.0, 50.0
	25 µg (56-70 years)	10	-1.00	11.52	0.00	-24.0, 20.0
	50 µg (56-70 years)	10	5.50	8.17	3.00	-1.0, 27.0
	100 µg (56-70 years)	10	1.10	8.54	-1.50	-7.0, 22.0
	All Subjects (56-70 years)	30	1.87	9.60	1.00	-24.0, 27.0
	25 µg (≥71 years)	10	-1.80	6.44	-4.50	-9.0, 9.0
	50 µg (≥71 years)	10	-13.70	40.99	0.00	-127.0, 12.0
	100 µg (≥71 years)	10	4.40	6.65	5.00	-8.0, 12.0
	All Subjects (≥71 years)	30	-3.70	24.62	1.50	-127.0, 12.0
	All Subjects	120	-0.24	15.91	0.40	-127.0, 50.0
N=Number of subjects in the Safety Population						

Table 147: Laboratory Results by Parameter, Severity, and Study Day
Any Hematology Parameter

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	13	87	2	13	-	-	-	-
	50 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	All Subjects (18-55 years)	60	60	55	92	5	8	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	8	80	2	20	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	3	10	-	-	-	-
	All Subjects	120	120	111	93	9	8	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	10	67	5	33	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	11	73	4	27	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	50	83	10	17	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	9	90	1	10	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	1	3	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	6	60	3	30	1	10	-	-
	All Subjects (≥71 years)	30	30	25	83	4	13	1	3	-	-
	All Subjects	120	120	104	87	15	13	1	1	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	5	36	9	64	-	-	-	-
	50 µg (18-55 years)	15	15	1	7	13	87	1	7	-	-
	100 µg (18-55 years)	15	15	5	33	10	67	-	-	-	-
	250 µg (18-55 years)	15	15	2	13	12	80	1	7	-	-
	All Subjects (18-55 years)	60	59	13	22	44	75	2	3	-	-
	25 µg (56-70 years)	10	10	1	10	7	70	2	20	-	-
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	All Subjects (56-70 years)	30	30	3	10	25	83	2	7	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	1	10	9	90	-	-	-	-
	50 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	100 µg (≥71 years)	10	10	-	-	10	100	-	-	-	-
	All Subjects (≥71 years)	30	30	3	10	27	90	-	-	-	-
	All Subjects	120	119	19	16	96	81	4	3	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	3	20	12	80	-	-	-	-
	50 µg (18-55 years)	15	15	5	33	10	67	-	-	-	-
	100 µg (18-55 years)	15	15	6	40	9	60	-	-	-	-
	250 µg (18-55 years)	15	14	4	29	10	71	-	-	-	-
	All Subjects (18-55 years)	60	59	18	31	41	69	-	-	-	-
	25 µg (56-70 years)	10	10	1	10	7	70	1	10	1	10
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	All Subjects (56-70 years)	30	30	3	10	25	83	1	3	1	3
	25 µg (≥71 years)	10	10	5	50	5	50	-	-	-	-
	50 µg (≥71 years)	10	10	4	40	6	60	-	-	-	-
	100 µg (≥71 years)	10	10	3	30	7	70	-	-	-	-
	All Subjects (≥71 years)	30	30	12	40	18	60	-	-	-	-
	All Subjects	120	119	33	28	84	71	1	1	1	1
	25 µg (18-55 years)	15	15	6	40	9	60	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	2	13	11	73	2	13	-	-
	100 µg (18-55 years)	15	15	4	27	11	73	-	-	-	-
	250 µg (18-55 years)	15	15	2	13	11	73	2	13	-	-
	All Subjects (18-55 years)	60	60	14	23	42	70	4	7	-	-
	25 µg (56-70 years)	10	10	3	30	7	70	-	-	-	-
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	-	-	9	90	1	10	-	-
	All Subjects (56-70 years)	30	30	4	13	25	83	1	3	-	-
	25 µg (≥71 years)	10	10	4	40	6	60	-	-	-	-
	50 µg (≥71 years)	10	10	3	30	7	70	-	-	-	-
	100 µg (≥71 years)	10	10	1	10	9	90	-	-	-	-
	All Subjects (≥71 years)	30	30	8	27	22	73	-	-	-	-
	All Subjects	120	120	26	22	89	74	5	4	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	1	7	14	93	-	-	-	-
	50 µg (18-55 years)	15	15	-	-	12	80	3	20	-	-
	100 µg (18-55 years)	15	15	3	20	12	80	-	-	-	-
	250 µg (18-55 years)	15	15	1	7	11	73	3	20	-	-
	All Subjects (18-55 years)	60	60	5	8	49	82	6	10	-	-
	25 µg (56-70 years)	10	10	-	-	7	70	2	20	1	10

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	-	-	10	100	-	-	-	-
	100 µg (56-70 years)	10	10	-	-	9	90	-	-	1	10
	All Subjects (56-70 years)	30	30	-	-	26	87	2	7	2	7
	25 µg (≥71 years)	10	10	-	-	10	100	-	-	-	-
	50 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	100 µg (≥71 years)	10	10	-	-	10	100	-	-	-	-
	All Subjects (≥71 years)	30	30	2	7	28	93	-	-	-	-
	All Subjects	120	120	7	6	103	86	8	7	2	2

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 148: Laboratory Results by Parameter, Severity, and Study Day
Hemoglobin

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	58	97	2	3	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	8	80	2	20	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	3	10	-	-	-	-
	All Subjects	120	120	115	96	5	4	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	12	80	3	20	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	12	80	3	20	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	53	88	7	12	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	8	80	2	20	-	-	-	-
	All Subjects (≥71 years)	30	30	27	90	3	10	-	-	-	-
	All Subjects	120	120	110	92	10	8	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	5	36	9	64	-	-	-	-
	50 µg (18-55 years)	15	15	1	7	13	87	1	7	-	-
	100 µg (18-55 years)	15	15	6	40	9	60	-	-	-	-
	250 µg (18-55 years)	15	15	3	20	11	73	1	7	-	-
	All Subjects (18-55 years)	60	59	15	25	42	71	2	3	-	-
	25 µg (56-70 years)	10	10	1	10	7	70	2	20	-	-
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	All Subjects (56-70 years)	30	30	3	10	25	83	2	7	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	1	10	9	90	-	-	-	-
	50 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	100 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	All Subjects (≥71 years)	30	30	5	17	25	83	-	-	-	-
	All Subjects	120	119	23	19	92	77	4	3	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	3	20	12	80	-	-	-	-
	50 µg (18-55 years)	15	15	5	33	10	67	-	-	-	-
	100 µg (18-55 years)	15	15	6	40	9	60	-	-	-	-
	250 µg (18-55 years)	15	14	4	29	10	71	-	-	-	-
	All Subjects (18-55 years)	60	59	18	31	41	69	-	-	-	-
	25 µg (56-70 years)	10	10	1	10	7	70	1	10	1	10
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	All Subjects (56-70 years)	30	30	3	10	25	83	1	3	1	3
	25 µg (≥71 years)	10	10	6	60	4	40	-	-	-	-
	50 µg (≥71 years)	10	10	4	40	6	60	-	-	-	-
	100 µg (≥71 years)	10	10	3	30	7	70	-	-	-	-
	All Subjects (≥71 years)	30	30	13	43	17	57	-	-	-	-
	All Subjects	120	119	34	29	83	70	1	1	1	1
	25 µg (18-55 years)	15	15	7	47	8	53	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	2	13	11	73	2	13	-	-
	100 µg (18-55 years)	15	15	4	27	11	73	-	-	-	-
	250 µg (18-55 years)	15	15	2	13	11	73	2	13	-	-
	All Subjects (18-55 years)	60	60	15	25	41	68	4	7	-	-
	25 µg (56-70 years)	10	10	3	30	7	70	-	-	-	-
	50 µg (56-70 years)	10	10	1	10	9	90	-	-	-	-
	100 µg (56-70 years)	10	10	-	-	9	90	1	10	-	-
	All Subjects (56-70 years)	30	30	4	13	25	83	1	3	-	-
	25 µg (≥71 years)	10	10	4	40	6	60	-	-	-	-
	50 µg (≥71 years)	10	10	3	30	7	70	-	-	-	-
	100 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	All Subjects (≥71 years)	30	30	9	30	21	70	-	-	-	-
	All Subjects	120	120	28	23	87	73	5	4	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	1	7	14	93	-	-	-	-
	50 µg (18-55 years)	15	15	-	-	12	80	3	20	-	-
	100 µg (18-55 years)	15	15	3	20	12	80	-	-	-	-
	250 µg (18-55 years)	15	15	2	13	10	67	3	20	-	-
	All Subjects (18-55 years)	60	60	6	10	48	80	6	10	-	-
	25 µg (56-70 years)	10	10	-	-	7	70	2	20	1	10

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	-	-	10	100	-	-	-	-
	100 µg (56-70 years)	10	10	-	-	9	90	-	-	1	10
	All Subjects (56-70 years)	30	30	-	-	26	87	2	7	2	7
	25 µg (≥71 years)	10	10	1	10	9	90	-	-	-	-
	50 µg (≥71 years)	10	10	2	20	8	80	-	-	-	-
	100 µg (≥71 years)	10	10	-	-	10	100	-	-	-	-
	All Subjects (≥71 years)	30	30	3	10	27	90	-	-	-	-
	All Subjects	120	120	9	8	101	84	8	7	2	2

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 149: Laboratory Results by Parameter, Severity, and Study Day
White Blood Cell Count

				None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	13	87	2	13	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	13	87	2	13	-	-	-	-	-	-	-	-	-	-

				None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	56	93	4	7	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	9	90	-	-	1	10	-	-	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	29	97	-	-	1	3	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	8	80	2	20	-	-	-	-	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	28	93	2	7	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	120	113	94	6	5	1	1	-	-	-	-	-	-	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	12	86	2	14	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	55	93	4	7	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-

				None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	29	97	1	3	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	119	114	96	5	4	-	-	-	-	-	-	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	13	87	2	13	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-	-	-	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	56	95	3	5	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	8	80	2	20	-	-	-	-	-	-	-	-	-	-

				None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (≥71 years)	30	30	28	93	2	7	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	119	114	96	5	4	-	-	-	-	-	-	-	-	-	-
Day 36 (Days 35 to 37)	**25 µg (18-55 years)**	15	15	13	87	2	13	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	57	95	3	5	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	7	70	3	30	-	-	-	-	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	26	87	4	13	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	120	113	94	7	6	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	11	73	4	27	-	-	-	-	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	13	87	2	13	-	-	-	-	-	-	-	-	-	-

				None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	250 µg (18-55 years)	15	15	14	93	1	7	-	-	-	-	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	53	88	7	12	-	-	-	-	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	7	70	3	30	-	-	-	-	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	26	87	4	13	-	-	-	-	-	-	-	-	-	-
	All Subjects	120	120	109	91	11	9	-	-	-	-	-	-	-	-	-	-

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 150: Laboratory Results by Parameter, Severity, and Study Day
Platelets

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screening (Day -42 to -1)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Day 1, Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	-	-	1	10	-	-
	All Subjects (≥71 years)	30	30	29	97	-	-	1	3	-	-
	All Subjects	120	120	119	99	-	-	1	1	-	-
Day 8 (Days 7 to 9)	**25 µg (18-55 years)**	15	14	14	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	29	97	1	3	-	-	-	-
	All Subjects	120	119	118	99	1	1	-	-	-	-
Day 29 (Days 27 to 31)	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	14	14	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	59	59	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	28	93	1	3	-	-	-	-
	All Subjects	120	119	117	98	1	1	-	-	-	-
	25 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 36 (Days 35 to 37)	**50 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (≥71 years)	30	30	30	100	-	-	-	-	-	-
	All Subjects	120	120	120	100	-	-	-	-	-	-
Max Severity Post Baseline	**25 µg (18-55 years)**	15	15	15	100	-	-	-	-	-	-
	50 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	100 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	250 µg (18-55 years)	15	15	15	100	-	-	-	-	-	-
	All Subjects (18-55 years)	60	60	60	100	-	-	-	-	-	-
	25 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Timepoint	**Treatment Group**	**N**	**N***	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	50 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (56-70 years)	10	10	10	100	-	-	-	-	-	-
	All Subjects (56-70 years)	30	30	30	100	-	-	-	-	-	-
	25 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	50 µg (≥71 years)	10	10	10	100	-	-	-	-	-	-
	100 µg (≥71 years)	10	10	9	90	1	10	-	-	-	-
	All Subjects (≥71 years)	30	30	28	93	2	7	-	-	-	-
	All Subjects	120	120	118	98	2	2	-	-	-	-

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 151: Shift Table of Laboratory Parameters – WBC

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	12	86	-	-	-	-	-	-
		Mild	-	-	2	14	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	12	80	1	7	-	-	-	-
		Mild	1	7	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	12	80	1	7	-	-	-	-
		Mild	1	7	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	13	87	-	-	-	-	-	-
		Mild	1	7	1	7	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	13	87	-	-	-	-	-	-
		Mild	1	7	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	13	87	-	-	-	-	-	-
		Mild	1	7	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	14	93	1	7	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	8	80	-	-	-	-	-	-
		Mild	1	10	1	10	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	7	70	1	10	-	-	-	-
		Mild	1	10	1	10	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	7	70	1	10	-	-	-	-
		Mild	-	-	2	20	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 152: Shift Table of Laboratory Parameters – Hemoglobin

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	4	29	7	50	-	-	-	-
		Mild	1	7	2	14	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	3	20	9	60	-	-	-	-
		Mild	-	-	3	20	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	6	40	6	40	-	-	-	-
		Mild	1	7	2	13	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	1	7	13	87	1	7	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	5	33	10	67	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	2	13	11	73	2	13	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	4	27	8	53	-	-	-	-
		Mild	2	13	1	7	-	-	-	-

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Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	4	27	8	53	-	-	-	-
		Mild	2	13	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	2	13	10	67	-	-	-	-
		Mild	2	13	1	7	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	2	13	11	73	1	7	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	3	21	10	71	-	-	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	1	7	11	73	2	13	-	-
		Mild	1	7	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	1	10	7	70	2	20	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	1	10	7	70	1	10	1	10

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	3	30	7	70	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	1	10	9	90	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	1	10	9	90	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	1	10	9	90	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	1	10	9	90	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	1	10	9	90	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	-	-	9	90	1	10	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	1	10	8	80	-	-	-	-
		Mild	-	-	1	10	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	5	50	4	40	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	3	30	6	60	-	-	-	-
		Mild	1	10	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	2	20	8	80	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	4	40	6	60	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	3	30	7	70	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	2	20	6	60	-	-	-	-
		Mild	-	-	2	20	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	1	10	7	70	-	-	-	-
		Mild	2	20	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	1	10	7	70	-	-	-	-
		Mild	1	10	1	10	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 153: Shift Table of Laboratory Parameters – Platelets

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
25 µg (18-55 years)	**Day 8 (N=14)**	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
250 µg (18-55 years)	**Day 8 (N=15)**	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=14)	**Normal**	14	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=15)	**Normal**	15	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
		Normal	10	100	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 29 (N=10)	**Mild**	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
100 µg (56-70 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
25 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	9	90	1	10	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
50 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	10	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-

Baseline Severity			Normal		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Treatment Group	**Time Point**	**Post-Baseline Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
		Severe	-	-	-	-	-	-	-	-
100 µg (≥71 years)	**Day 8 (N=10)**	**Normal**	9	90	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	1	10	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 29 (N=9)	**Normal**	9	100	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	-	-	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
	Day 36 (N=10)	**Normal**	9	90	-	-	-	-	-	-
		Mild	-	-	-	-	-	-	-	-
		Moderate	1	10	-	-	-	-	-	-
		Severe	-	-	-	-	-	-	-	-
N = Number of subjects that completed the visit and data available at both baseline and corresponding timepoint.										

Table 154: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Hemoglobin

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	14.09	1.47	14.30	11.7, 16.2
	50 µg (18-55 years)	15	14.51	0.90	14.30	13.3, 16.2
	100 µg (18-55 years)	15	13.87	1.47	13.70	11.1, 16.7
	250 µg (18-55 years)	15	14.15	1.51	14.00	12.0, 16.7
	All Subjects (18-55 years)	60	14.16	1.35	14.10	11.1, 16.7
	25 µg (56-70 years)	10	14.45	1.21	14.70	12.8, 16.8
	50 µg (56-70 years)	10	14.36	1.50	14.95	12.2, 16.3
	100 µg (56-70 years)	10	14.39	0.92	14.35	13.0, 15.7
	All Subjects (56-70 years)	30	14.40	1.19	14.70	12.2, 16.8
	25 µg (≥71 years)	10	14.15	0.80	14.10	12.8, 15.4
	50 µg (≥71 years)	10	14.59	0.94	14.65	13.4, 16.4
	100 µg (≥71 years)	10	13.25	1.36	12.80	11.7, 15.5
	All Subjects (≥71 years)	30	14.00	1.17	14.10	11.7, 16.4
	All Subjects	120	14.18	1.26	14.20	11.1, 16.8
Day 8	25 µg (18-55 years)	14	13.83	1.56	13.75	11.3, 16.2
	50 µg (18-55 years)	15	13.91	1.04	13.90	12.2, 15.5
	100 µg (18-55 years)	15	13.72	1.48	13.70	10.5, 15.9
	250 µg (18-55 years)	15	13.68	1.19	13.80	11.4, 15.7
	All Subjects (18-55 years)	59	13.78	1.30	13.80	10.5, 16.2
	25 µg (56-70 years)	10	13.62	1.04	13.60	11.7, 14.8
	50 µg (56-70 years)	10	13.79	1.71	14.45	11.3, 15.8
	100 µg (56-70 years)	10	13.79	0.99	13.80	12.5, 15.2
	All Subjects (56-70 years)	30	13.73	1.25	13.80	11.3, 15.8
	25 µg (≥71 years)	10	13.68	0.85	13.65	12.3, 14.8
	50 µg (≥71 years)	10	14.19	0.76	14.45	12.9, 15.1
	100 µg (≥71 years)	10	12.92	1.51	12.55	11.0, 15.6
	All Subjects (≥71 years)	30	13.60	1.18	13.60	11.0, 15.6
	All Subjects	119	13.72	1.25	13.70	10.5, 16.2
Day 8, Change from Baseline	25 µg (18-55 years)	14	-0.24	0.47	-0.15	-1.4, 0.4
	50 µg (18-55 years)	15	-0.61	0.71	-0.60	-1.9, 1.4
	100 µg (18-55 years)	15	-0.15	0.65	-0.20	-1.2, 1.1
	250 µg (18-55 years)	15	-0.47	0.74	-0.50	-1.6, 0.9
	All Subjects (18-55 years)	59	-0.37	0.66	-0.40	-1.9, 1.4
	25 µg (56-70 years)	10	-0.83	0.68	-0.80	-2.0, 0.0
	50 µg (56-70 years)	10	-0.57	0.29	-0.60	-0.9, 0.0
	100 µg (56-70 years)	10	-0.60	0.27	-0.65	-0.9, 0.0
	All Subjects (56-70 years)	30	-0.67	0.46	-0.60	-2.0, 0.0
	25 µg (≥71 years)	10	-0.47	0.36	-0.45	-1.1, 0.1
	50 µg (≥71 years)	10	-0.40	0.93	-0.25	-1.9, 1.6

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	-0.33	0.43	-0.30	-1.1, 0.3
	All Subjects (≥71 years)	30	-0.40	0.61	-0.40	-1.9, 1.6
	All Subjects	119	-0.45	0.61	-0.50	-2.0, 1.6
Day 29	25 µg (18-55 years)	15	13.79	1.62	13.80	10.6, 15.8
	50 µg (18-55 years)	15	14.10	1.30	13.70	11.5, 16.5
	100 µg (18-55 years)	15	13.57	1.51	13.80	10.3, 15.3
	250 µg (18-55 years)	14	13.94	1.57	13.65	11.7, 16.2
	All Subjects (18-55 years)	59	13.85	1.48	13.80	10.3, 16.5
	25 µg (56-70 years)	10	13.59	1.17	14.00	12.1, 15.5
	50 µg (56-70 years)	10	13.90	1.48	14.40	12.2, 16.0
	100 µg (56-70 years)	10	13.79	1.09	13.90	12.3, 15.4
	All Subjects (56-70 years)	30	13.76	1.22	14.05	12.1, 16.0
	25 µg (≥71 years)	10	14.26	0.82	14.45	12.6, 15.1
	50 µg (≥71 years)	10	14.33	0.86	14.50	13.1, 15.6
	100 µg (≥71 years)	10	13.13	1.24	12.60	11.6, 15.3
	All Subjects (≥71 years)	30	13.91	1.11	14.15	11.6, 15.6
	All Subjects	119	13.84	1.32	13.90	10.3, 16.5
Day 29, Change from Baseline	25 µg (18-55 years)	15	-0.31	0.54	-0.40	-1.1, 0.9
	50 µg (18-55 years)	15	-0.41	0.71	-0.30	-1.9, 0.5
	100 µg (18-55 years)	15	-0.29	0.73	-0.50	-1.4, 0.9
	250 µg (18-55 years)	14	-0.32	0.66	-0.55	-1.1, 0.9
	All Subjects (18-55 years)	59	-0.33	0.65	-0.40	-1.9, 0.9
	25 µg (56-70 years)	10	-0.86	0.90	-0.75	-2.7, 0.7
	50 µg (56-70 years)	10	-0.46	0.30	-0.40	-1.0, 0.0
	100 µg (56-70 years)	10	-0.60	0.53	-0.40	-1.5, 0.0
	All Subjects (56-70 years)	30	-0.64	0.63	-0.55	-2.7, 0.7
	25 µg (≥71 years)	10	0.11	0.50	0.05	-0.7, 1.0
	50 µg (≥71 years)	10	-0.26	0.84	-0.35	-1.1, 1.5
	100 µg (≥71 years)	10	-0.12	0.38	-0.20	-0.5, 0.6
	All Subjects (≥71 years)	30	-0.09	0.60	-0.20	-1.1, 1.5
	All Subjects	119	-0.35	0.66	-0.40	-2.7, 1.5
Day 36	25 µg (18-55 years)	15	13.95	1.65	13.90	11.2, 16.3
	50 µg (18-55 years)	15	13.59	0.85	13.40	11.9, 14.8
	100 µg (18-55 years)	15	13.56	1.36	13.80	10.6, 15.9
	250 µg (18-55 years)	15	13.55	1.42	13.60	11.6, 16.2
	All Subjects (18-55 years)	60	13.66	1.33	13.70	10.6, 16.3
	25 µg (56-70 years)	10	13.76	1.25	13.75	11.4, 15.5
	50 µg (56-70 years)	10	13.74	1.73	14.30	11.3, 16.3
	100 µg (56-70 years)	10	13.45	1.02	13.10	12.1, 14.8
	All Subjects (56-70 years)	30	13.65	1.33	13.75	11.3, 16.3
	25 µg (≥71 years)	10	13.98	0.60	14.10	12.7, 14.8

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	14.20	0.87	14.20	12.8, 15.4
	100 µg (≥71 years)	10	13.01	1.36	12.50	11.7, 15.4
	All Subjects (≥71 years)	30	13.73	1.09	14.05	11.7, 15.4
	All Subjects	120	13.68	1.26	13.80	10.6, 16.3
Day 36, Change from Baseline	25 µg (18-55 years)	15	-0.15	0.56	-0.40	-1.0, 1.0
	50 µg (18-55 years)	15	-0.93	0.68	-1.00	-1.9, 0.4
	100 µg (18-55 years)	15	-0.31	0.67	-0.50	-1.3, 1.2
	250 µg (18-55 years)	15	-0.60	0.69	-0.60	-1.8, 0.6
	All Subjects (18-55 years)	60	-0.50	0.70	-0.50	-1.9, 1.2
	25 µg (56-70 years)	10	-0.69	0.71	-0.95	-1.5, 0.5
	50 µg (56-70 years)	10	-0.62	0.31	-0.60	-1.0, 0.0
	100 µg (56-70 years)	10	-0.94	0.42	-0.90	-1.9, -0.3
	All Subjects (56-70 years)	30	-0.75	0.51	-0.90	-1.9, 0.5
	25 µg (≥71 years)	10	-0.17	0.55	-0.10	-1.3, 0.7
	50 µg (≥71 years)	10	-0.39	0.85	-0.55	-1.3, 1.5
	100 µg (≥71 years)	10	-0.24	0.44	-0.20	-1.2, 0.4
	All Subjects (≥71 years)	30	-0.27	0.62	-0.25	-1.3, 1.5
	All Subjects	120	-0.50	0.66	-0.50	-1.9, 1.5
N=Number of subjects in the Safety Population						

Table 155: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – Platelets

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	244.0	42.2	248.0	172, 317
	50 µg (18-55 years)	15	244.7	32.6	241.0	206, 330
	100 µg (18-55 years)	15	248.0	50.8	245.0	168, 334
	250 µg (18-55 years)	15	241.8	50.2	243.0	182, 373
	All Subjects (18-55 years)	60	244.6	43.5	243.0	168, 373
	25 µg (56-70 years)	10	258.2	80.2	249.5	167, 395
	50 µg (56-70 years)	10	214.2	35.3	215.0	153, 262
	100 µg (56-70 years)	10	271.9	55.5	267.0	199, 355
	All Subjects (56-70 years)	30	248.1	63.0	227.0	153, 395
	25 µg (≥71 years)	10	213.6	58.5	205.5	142, 333
	50 µg (≥71 years)	10	210.7	51.2	198.5	154, 321
	100 µg (≥71 years)	10	237.6	86.8	202.0	104, 369
	All Subjects (≥71 years)	30	220.6	66.0	200.5	104, 369
	All Subjects	120	239.5	55.6	229.0	104, 395
Day 8	25 µg (18-55 years)	14	256.6	45.8	252.0	167, 324
	50 µg (18-55 years)	15	238.5	30.6	239.0	194, 316
	100 µg (18-55 years)	15	260.6	57.7	251.0	174, 379
	250 µg (18-55 years)	15	248.6	59.6	248.0	186, 420
	All Subjects (18-55 years)	59	251.0	49.3	248.0	167, 420
	25 µg (56-70 years)	10	253.0	81.9	243.0	159, 388
	50 µg (56-70 years)	10	219.6	28.0	227.5	160, 252
	100 µg (56-70 years)	10	274.6	55.8	269.5	215, 370
	All Subjects (56-70 years)	30	249.1	61.8	232.5	159, 388
	25 µg (≥71 years)	10	229.5	58.8	219.0	152, 354
	50 µg (≥71 years)	10	212.7	53.8	203.5	160, 350
	100 µg (≥71 years)	10	238.5	77.8	213.0	125, 363
	All Subjects (≥71 years)	30	226.9	63.0	212.0	125, 363
	All Subjects	119	244.4	56.7	232.0	125, 420
Day 8, Change from Baseline	25 µg (18-55 years)	14	9.5	22.5	9.5	-37, 44
	50 µg (18-55 years)	15	-6.2	15.4	-11.0	-29, 29
	100 µg (18-55 years)	15	12.6	22.0	15.0	-43, 58
	250 µg (18-55 years)	15	6.8	16.3	3.0	-17, 47
	All Subjects (18-55 years)	59	5.6	20.1	6.0	-43, 58
	25 µg (56-70 years)	10	-5.2	16.7	-5.5	-39, 19
	50 µg (56-70 years)	10	5.4	14.8	8.0	-20, 22
	100 µg (56-70 years)	10	2.7	12.8	-0.5	-11, 19
	All Subjects (56-70 years)	30	1.0	15.1	-1.5	-39, 22
	25 µg (≥71 years)	10	15.9	7.9	13.5	9, 35
	50 µg (≥71 years)	10	2.0	22.4	6.0	-45, 29

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	0.9	15.2	0.5	-23, 24
	All Subjects (≥71 years)	30	6.3	17.1	10.0	-45, 35
	All Subjects	119	4.6	18.2	6.0	-45, 58
Day 29	25 µg (18-55 years)	15	247.8	48.0	249.0	148, 309
	50 µg (18-55 years)	15	236.5	25.3	237.0	188, 289
	100 µg (18-55 years)	15	246.4	56.6	235.0	170, 367
	250 µg (18-55 years)	14	237.9	61.6	216.0	174, 415
	All Subjects (18-55 years)	59	242.2	48.6	235.0	148, 415
	25 µg (56-70 years)	10	251.2	70.4	246.0	163, 352
	50 µg (56-70 years)	10	214.7	34.0	216.0	164, 267
	100 µg (56-70 years)	10	265.1	57.1	263.5	202, 358
	All Subjects (56-70 years)	30	243.7	58.1	224.0	163, 358
	25 µg (≥71 years)	10	226.3	67.9	215.5	137, 354
	50 µg (≥71 years)	10	219.8	62.1	198.5	163, 327
	100 µg (≥71 years)	9	251.1	81.6	202.0	165, 384
	All Subjects (≥71 years)	29	231.8	69.3	205.0	137, 384
	All Subjects	118	240.0	56.4	231.0	137, 415
Day 29, Change from Baseline	25 µg (18-55 years)	15	3.8	19.3	7.0	-25, 34
	50 µg (18-55 years)	15	-8.1	26.9	-13.0	-42, 33
	100 µg (18-55 years)	15	-1.6	26.7	-10.0	-56, 54
	250 µg (18-55 years)	14	-1.3	24.2	7.0	-33, 42
	All Subjects (18-55 years)	59	-1.8	24.2	-3.0	-56, 54
	25 µg (56-70 years)	10	-7.0	22.3	-2.0	-45, 23
	50 µg (56-70 years)	10	0.5	18.9	4.0	-38, 33
	100 µg (56-70 years)	10	-6.8	14.1	-2.0	-33, 10
	All Subjects (56-70 years)	30	-4.4	18.4	-0.5	-45, 33
	25 µg (≥71 years)	10	12.7	14.8	16.5	-9, 38
	50 µg (≥71 years)	10	9.1	24.6	6.0	-23, 72
	100 µg (≥71 years)	9	-1.3	13.1	2.0	-22, 15
	All Subjects (≥71 years)	29	7.1	18.7	6.0	-23, 72
	All Subjects	118	-0.3	21.9	1.0	-56, 72
Day 36	25 µg (18-55 years)	15	258.3	48.9	272.0	163, 335
	50 µg (18-55 years)	15	248.1	25.6	235.0	223, 306
	100 µg (18-55 years)	15	269.7	56.9	267.0	162, 366
	250 µg (18-55 years)	15	258.1	54.9	253.0	190, 407
	All Subjects (18-55 years)	60	258.6	47.6	255.0	162, 407
	25 µg (56-70 years)	10	268.0	71.6	268.5	187, 379
	50 µg (56-70 years)	10	233.1	43.0	241.5	148, 282
	100 µg (56-70 years)	10	288.3	59.1	283.5	226, 379
	All Subjects (56-70 years)	30	263.1	61.5	258.0	148, 379
	25 µg (≥71 years)	10	229.2	68.3	213.0	150, 378

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	50 µg (≥71 years)	10	218.0	54.2	209.5	157, 342
	100 µg (≥71 years)	10	248.8	84.6	217.0	141, 391
	All Subjects (≥71 years)	30	232.0	68.9	211.5	141, 391
	All Subjects	120	253.1	57.9	245.5	141, 407
Day 36, Change from Baseline	25 µg (18-55 years)	15	14.3	21.3	10.0	-22, 50
	50 µg (18-55 years)	15	3.4	16.0	0.0	-24, 24
	100 µg (18-55 years)	15	21.7	24.5	27.0	-30, 70
	250 µg (18-55 years)	15	16.3	24.8	18.0	-40, 52
	All Subjects (18-55 years)	60	13.9	22.4	17.5	-40, 70
	25 µg (56-70 years)	10	9.8	20.5	13.0	-21, 39
	50 µg (56-70 years)	10	18.9	20.4	13.5	-5, 60
	100 µg (56-70 years)	10	16.4	16.6	15.0	-6, 46
	All Subjects (56-70 years)	30	15.0	19.0	13.5	-21, 60
	25 µg (≥71 years)	10	15.6	14.9	13.5	-5, 45
	50 µg (≥71 years)	10	7.3	13.4	10.0	-15, 26
	100 µg (≥71 years)	10	11.2	18.4	13.5	-33, 37
	All Subjects (≥71 years)	30	11.4	15.5	12.0	-33, 45
	All Subjects	120	13.6	19.9	14.5	-40, 70
N=Number of subjects in the Safety Population						

Table 156: Laboratory Summary Statistics by Parameter, Time Point, and Treatment Group – WBC

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
Baseline	25 µg (18-55 years)	15	5.220	1.401	5.000	2.90, 8.80
	50 µg (18-55 years)	15	6.000	1.255	6.100	4.30, 8.70
	100 µg (18-55 years)	15	5.340	1.471	5.100	3.20, 8.30
	250 µg (18-55 years)	15	5.573	1.114	5.100	4.00, 7.40
	All Subjects (18-55 years)	60	5.533	1.318	5.300	2.90, 8.80
	25 µg (56-70 years)	10	6.050	1.147	5.850	4.20, 8.60
	50 µg (56-70 years)	10	6.046	2.410	5.350	3.87, 11.98
	100 µg (56-70 years)	10	6.010	1.029	6.400	4.60, 7.40
	All Subjects (56-70 years)	30	6.035	1.594	5.840	3.87, 11.98
	25 µg (≥71 years)	10	4.970	1.073	5.150	3.60, 6.60
	50 µg (≥71 years)	10	5.743	0.929	5.745	4.09, 7.14
	100 µg (≥71 years)	10	4.750	1.114	4.450	3.10, 6.60
	All Subjects (≥71 years)	30	5.154	1.094	5.375	3.10, 7.14
	All Subjects	120	5.564	1.368	5.400	2.90, 11.98
Day 8	25 µg (18-55 years)	14	5.357	1.339	5.550	3.20, 8.10
	50 µg (18-55 years)	15	5.993	1.054	6.200	4.50, 8.00
	100 µg (18-55 years)	15	5.180	1.480	4.900	2.80, 8.10
	250 µg (18-55 years)	15	5.333	1.152	5.100	3.40, 8.10
	All Subjects (18-55 years)	59	5.468	1.273	5.400	2.80, 8.10
	25 µg (56-70 years)	10	6.330	1.705	5.950	4.30, 9.90
	50 µg (56-70 years)	10	5.878	1.719	5.540	4.02, 9.81
	100 µg (56-70 years)	10	5.760	0.947	5.700	4.40, 7.30
	All Subjects (56-70 years)	30	5.989	1.469	5.630	4.02, 9.90
	25 µg (≥71 years)	10	5.840	1.007	6.100	4.30, 7.30
	50 µg (≥71 years)	10	5.686	0.990	5.680	3.84, 7.33
	100 µg (≥71 years)	10	5.340	1.395	5.450	3.30, 7.50
	All Subjects (≥71 years)	30	5.622	1.126	5.710	3.30, 7.50
	All Subjects	119	5.638	1.298	5.540	2.80, 9.90
Day 8, Change from Baseline	25 µg (18-55 years)	14	0.093	0.920	0.150	-1.60, 1.90
	50 µg (18-55 years)	15	-0.007	0.877	0.100	-2.50, 1.30
	100 µg (18-55 years)	15	-0.160	0.415	-0.100	-0.90, 0.70
	250 µg (18-55 years)	15	-0.240	0.694	-0.200	-1.70, 1.00
	All Subjects (18-55 years)	59	-0.081	0.742	0.000	-2.50, 1.90
	25 µg (56-70 years)	10	0.280	0.981	0.350	-1.50, 1.60
	50 µg (56-70 years)	10	-0.168	1.084	0.150	-2.17, 0.96
	100 µg (56-70 years)	10	-0.250	0.950	-0.200	-2.20, 1.30
	All Subjects (56-70 years)	30	-0.046	1.000	-0.050	-2.20, 1.60
	25 µg (≥71 years)	10	0.870	0.665	0.800	-0.10, 1.90
	50 µg (≥71 years)	10	-0.057	0.738	0.130	-1.32, 0.93
	100 µg (≥71 years)	10	0.590	0.567	0.700	-0.30, 1.20

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	All Subjects (≥71 years)	30	0.468	0.750	0.650	-1.32, 1.90
	All Subjects	119	0.066	0.842	0.080	-2.50, 1.90
Day 29	25 µg (18-55 years)	15	4.827	1.362	4.600	2.80, 8.10
	50 µg (18-55 years)	15	5.627	1.026	5.700	3.80, 7.50
	100 µg (18-55 years)	15	5.473	1.378	5.300	3.30, 8.40
	250 µg (18-55 years)	14	5.443	1.283	5.250	3.90, 7.90
	All Subjects (18-55 years)	59	5.341	1.275	5.200	2.80, 8.40
	25 µg (56-70 years)	10	6.240	1.397	6.150	4.40, 8.60
	50 µg (56-70 years)	10	5.510	0.846	5.575	4.44, 6.82
	100 µg (56-70 years)	10	5.310	1.127	5.150	4.00, 7.60
	All Subjects (56-70 years)	30	5.687	1.178	5.600	4.00, 8.60
	25 µg (≥71 years)	10	4.900	1.058	4.950	3.70, 6.70
	50 µg (≥71 years)	10	5.803	1.228	6.190	3.74, 7.77
	100 µg (≥71 years)	10	4.970	1.522	4.600	3.30, 8.00
	All Subjects (≥71 years)	30	5.224	1.307	5.115	3.30, 8.00
	All Subjects	119	5.399	1.261	5.200	2.80, 8.60
Day 29, Change from Baseline	25 µg (18-55 years)	15	-0.393	0.782	-0.400	-1.80, 1.30
	50 µg (18-55 years)	15	-0.373	0.848	-0.300	-2.60, 1.20
	100 µg (18-55 years)	15	0.133	0.589	0.200	-1.00, 1.10
	250 µg (18-55 years)	14	-0.007	0.715	-0.200	-0.80, 1.70
	All Subjects (18-55 years)	59	-0.163	0.757	-0.200	-2.60, 1.70
	25 µg (56-70 years)	10	0.190	0.956	0.300	-1.40, 1.80
	50 µg (56-70 years)	10	-0.536	1.867	0.205	-5.16, 1.23
	100 µg (56-70 years)	10	-0.700	1.152	-0.550	-2.30, 1.00
	All Subjects (56-70 years)	30	-0.349	1.390	0.115	-5.16, 1.80
	25 µg (≥71 years)	10	-0.070	0.745	-0.300	-1.40, 1.00
	50 µg (≥71 years)	10	0.060	0.793	-0.105	-1.19, 1.34
	100 µg (≥71 years)	10	0.220	0.658	0.200	-1.10, 1.40
	All Subjects (≥71 years)	30	0.070	0.719	0.000	-1.40, 1.40
	All Subjects	119	-0.151	0.952	-0.100	-5.16, 1.80
Day 36	25 µg (18-55 years)	15	4.967	1.180	4.900	2.70, 7.50
	50 µg (18-55 years)	15	5.827	1.163	6.300	4.00, 7.30
	100 µg (18-55 years)	15	5.220	1.353	5.100	3.00, 8.20
	250 µg (18-55 years)	15	5.407	0.942	5.500	3.80, 6.90
	All Subjects (18-55 years)	60	5.355	1.182	5.300	2.70, 8.20
	25 µg (56-70 years)	10	6.180	1.365	6.400	4.10, 8.50
	50 µg (56-70 years)	10	5.717	1.227	5.710	4.28, 8.15
	100 µg (56-70 years)	10	6.040	1.613	5.750	3.90, 9.10
	All Subjects (56-70 years)	30	5.979	1.376	5.855	3.90, 9.10
	25 µg (≥71 years)	10	5.060	0.900	4.900	3.20, 6.20
	50 µg (≥71 years)	10	6.028	1.120	6.015	3.89, 7.53

Time Point	Treatment Group	N	Mean	Standard Deviation	Median	Min, Max
	100 µg (≥71 years)	10	4.600	1.026	4.650	3.20, 5.90
	All Subjects (≥71 years)	30	5.229	1.155	5.400	3.20, 7.53
	All Subjects	120	5.480	1.251	5.450	2.70, 9.10
Day 36, Change from Baseline	25 µg (18-55 years)	15	-0.253	0.794	-0.400	-1.40, 1.20
	50 µg (18-55 years)	15	-0.173	1.039	0.100	-3.00, 1.00
	100 µg (18-55 years)	15	-0.120	0.512	-0.100	-1.20, 0.60
	250 µg (18-55 years)	15	-0.167	0.794	-0.300	-1.30, 0.80
	All Subjects (18-55 years)	60	-0.178	0.787	-0.150	-3.00, 1.20
	25 µg (56-70 years)	10	0.130	1.044	0.400	-1.70, 1.20
	50 µg (56-70 years)	10	-0.329	1.332	0.225	-3.83, 0.73
	100 µg (56-70 years)	10	0.030	1.626	-0.550	-1.50, 3.60
	All Subjects (56-70 years)	30	-0.056	1.323	-0.200	-3.83, 3.60
	25 µg (≥71 years)	10	0.090	0.906	0.300	-1.50, 1.30
	50 µg (≥71 years)	10	0.285	1.273	0.145	-2.06, 2.32
	100 µg (≥71 years)	10	-0.150	0.530	0.000	-1.00, 0.60
	All Subjects (≥71 years)	30	0.075	0.937	0.150	-2.06, 2.32
	All Subjects	120	-0.085	0.979	-0.100	-3.83, 3.60
N=Number of subjects in the Safety Population						

Figure 123: Clinical Laboratory Results by Severity and Treatment Group 18-55 Years of Age

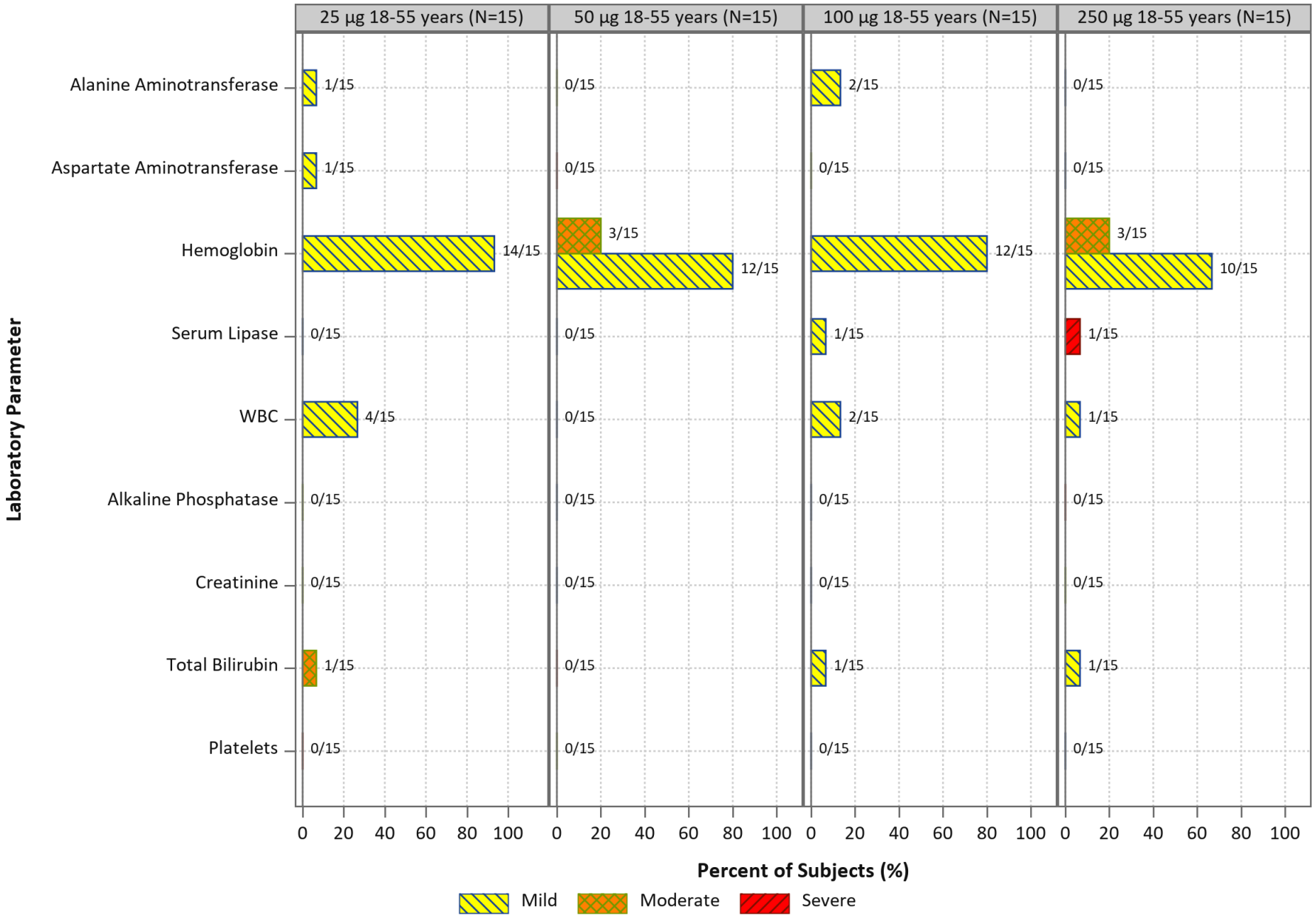
25 µg 18-55 years (N=15)
50 µg 18-55 years (N=15)
100 µg 18-55 years (N=15)
250 µg 18-55 years (N=15)
Laboratory Parameter
Alanine Aminotransferase
Aspartate Aminotransferase
Hemoglobin
Serum Lipase
WBC
Alkaline Phosphatase
Creatinine
Total Bilirubin
Platelets
1/15
0/15
2/15
0/15
1/15
0/15
3/15
14/15
12/15
3/15
12/15
10/15
0/15
0/15
1/15
1/15
4/15
0/15
2/15
1/15
0/15
0/15
0/15
0/15
0/15
0/15
0/15
0/15
1/15
0/15
1/15
1/15
0/15
0/15
0/15
0/15
0 20 40 60 80 100
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 124: Clinical Laboratory Results by Severity and Treatment Group 56-70 Years of Age

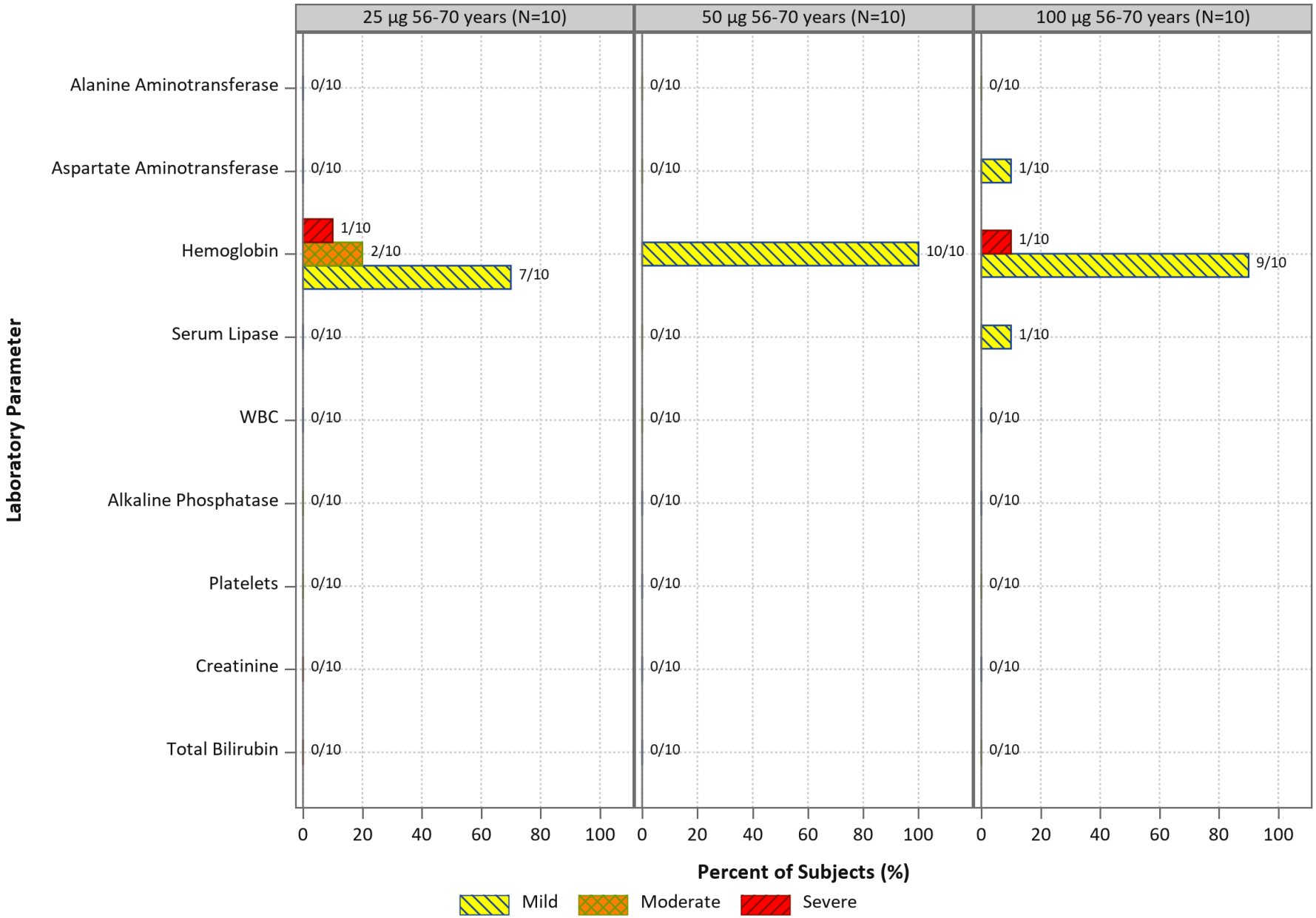
25 µg 56-70 years (N=10)
50 µg 56-70 years (N=10)
100 µg 56-70 years (N=10)
Laboratory Parameter
Alanine Aminotransferase
Aspartate Aminotransferase
Hemoglobin
Serum Lipase
WBC
Alkaline Phosphatase
Platelets
Creatinine
Total Bilirubin
0/10
1/10
2/10
7/10
10/10
9/10
0
20
40
60
80
100
Percent of Subjects (%)
Mild
Moderate
Severe

Figure 125: Clinical Laboratory Results by Severity and Treatment Group ≥71 years of Age

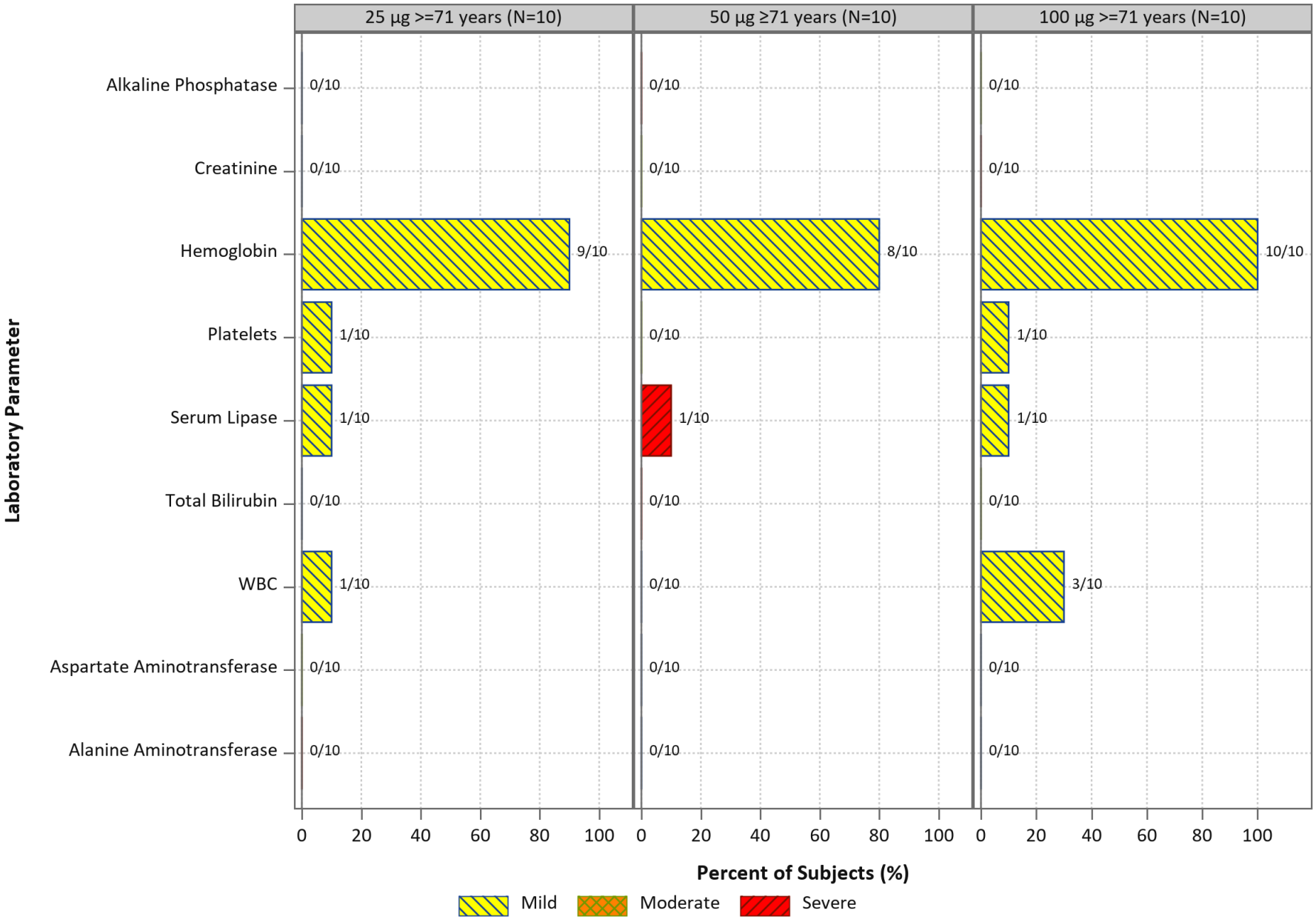
25 µg >=71 years (N=10)
50 µg ≥71 years (N=10)
100 µg >=71 years (N=10)
Laboratory Parameter
Alkaline Phosphatase
Creatinine
Hemoglobin
Platelets
Serum Lipase
Total Bilirubin
WBC
Aspartate Aminotransferase
Alanine Aminotransferase
0/10
9/10
8/10
10/10
1/10
3/10
0
20
40
60
80
100
Percent of Subjects (%)
Mild
Moderate
Severe

Table 157: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age

Any Assessment											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%
Baseline	None	15	100	13	87	14	93	15	100	57	95
	Mild	-	-	2	13	1	7	-	-	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 8	None	14	93	14	93	15	100	13	87	56	93
	Mild	-	-	1	7	-	-	2	13	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 15	None	15	100	14	93	14	93	14	93	57	95
	Mild	-	-	1	7	1	7	1	7	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 29	None	13	87	14	93	15	100	13	87	55	92
	Mild	2	13	1	7	-	-	1	7	4	7
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 36	None	15	100	13	87	15	100	14	93	57	95
	Mild	-	-	2	13	-	-	1	7	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 43	None	15	100	12	80	13	87	14	93	54	90
	Mild	-	-	2	13	1	7	1	7	4	7
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Any Assessment											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	15	100	14	93	14	93	15	100	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 119	**None**	15	100	10	67	15	100	14	93	54	90
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	13	87	11	73	13	87	12	80	49	82
	Mild	2	13	4	27	2	13	2	13	10	17
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 158: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age

Systolic Blood Pressure											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%
Baseline	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 8	None	14	93	15	100	15	100	14	93	58	97
	Mild	-	-	-	-	-	-	1	7	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 15	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 29	None	13	87	15	100	15	100	13	87	56	93
	Mild	2	13	-	-	-	-	1	7	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 36	None	15	100	15	100	15	100	14	93	59	98
	Mild	-	-	-	-	-	-	1	7	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 43	None	15	100	14	93	14	93	15	100	58	97
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Systolic Blood Pressure											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	15	100	15	100	14	93	15	100	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 119	**None**	15	100	11	73	15	100	15	100	56	93
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	13	87	15	100	15	100	13	87	56	93
	Mild	2	13	-	-	-	-	2	13	4	7
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 159: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age

Diastolic Blood Pressure											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%
Baseline	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 8	None	14	93	15	100	15	100	14	93	58	97
	Mild	-	-	-	-	-	-	1	7	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 15	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 29	None	15	100	15	100	15	100	14	93	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 36	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 43	None	15	100	14	93	14	93	15	100	58	97
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Diastolic Blood Pressure											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	15	100	15	100	14	93	15	100	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 119	**None**	15	100	11	73	15	100	15	100	56	93
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	15	100	15	100	15	100	14	93	59	98
	Mild	-	-	-	-	-	-	1	7	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 160: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age

Pulse Rate											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%
Baseline	None	15	100	13	87	14	93	15	100	57	95
	Mild	-	-	2	13	1	7	-	-	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 8	None	14	93	14	93	15	100	15	100	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 15	None	15	100	14	93	14	93	14	93	57	95
	Mild	-	-	1	7	1	7	1	7	3	5
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 29	None	15	100	14	93	15	100	14	93	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 36	None	15	100	13	87	15	100	15	100	58	97
	Mild	-	-	2	13	-	-	-	-	2	3
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 43	None	15	100	12	80	13	87	14	93	54	90
	Mild	-	-	2	13	1	7	1	7	4	7
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Pulse Rate											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	15	100	14	93	14	93	15	100	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 119	**None**	15	100	10	67	15	100	14	93	54	90
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	15	100	11	73	13	87	14	93	53	88
	Mild	-	-	4	27	2	13	-	-	6	10
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments. N = Number of subjects in the Safety Population.											

Table 161: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 18-55 Years of Age

Temperature											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%
Baseline	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 8	None	14	93	15	100	15	100	15	100	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 15	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 29	None	15	100	15	100	15	100	14	93	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 36	None	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 43	None	15	100	14	93	14	93	15	100	58	97
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Temperature											
		25 µg mRNA-1273 (N=15)		50 µg mRNA -1273 (N=15)		100 µg mRNA -1273 (N=15)		250 µg mRNA -1273 (N=15)		All Subjects (N=60)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	15	100	15	100	14	93	15	100	59	98
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 119	**None**	15	100	11	73	15	100	15	100	56	93
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	15	100	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 162: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age

Any Assessment									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	7	70	8	80	7	70	22	73
	Mild	3	30	2	20	3	30	8	27
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	9	90	9	90	8	80	26	87
	Mild	1	10	1	10	2	20	4	13
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	8	80	28	93
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	1	10	1	3
	Severe	-	-	-	-	-	-	-	-
Day 29	None	8	80	9	90	9	90	26	87
	Mild	2	20	1	10	1	10	4	13
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	9	90	29	97
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Any Assessment									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	9	90	10	100	10	100	29	97
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	8	80	10	100	9	90	27	90
	Mild	1	10	-	-	1	10	2	7
	Moderate	1	10	-	-	-	-	1	3
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	8	80	8	80	6	60	22	73
	Mild	1	10	2	20	3	30	6	20
	Moderate	1	10	-	-	1	10	2	7
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 163: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age

Systolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	7	70	9	90	8	80	24	80
	Mild	3	30	1	10	2	20	6	20
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	9	90	10	100	8	80	27	90
	Mild	1	10	-	-	2	20	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	8	80	28	93
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	1	10	1	3
	Severe	-	-	-	-	-	-	-	-
Day 29	None	9	90	10	100	9	90	28	93
	Mild	1	10	-	-	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	9	90	29	97
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Systolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	9	90	10	100	10	100	29	97
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	8	80	10	100	9	90	27	90
	Mild	1	10	-	-	1	10	2	7
	Moderate	1	10	-	-	-	-	1	3
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	8	80	10	100	6	60	24	80
	Mild	1	10	-	-	3	30	4	13
	Moderate	1	10	-	-	1	10	2	7
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 164: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age

Diastolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	9	90	10	100	8	80	27	90
	Mild	1	10	-	-	2	20	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	9	90	29	97
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	9	90	10	100	9	90	28	93
	Mild	1	10	-	-	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Diastolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	9	90	10	100	10	100	29	97
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	9	90	10	100	9	90	28	93
	Mild	1	10	-	-	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 165: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age

Pulse Rate									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Pulse Rate									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 57	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	10	100	8	80	10	100	28	93
	Mild	-	-	2	20	-	-	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 166: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects 56-70 Years of Age

Temperature									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	10	100	10	100	10	100	30	100

Temperature									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 167: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

Any Assessment									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	7	70	7	70	9	90	23	77
	Mild	3	30	3	30	1	10	7	23
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	9	90	8	80	8	80	25	83
	Mild	1	10	2	20	2	20	5	17
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	9	90	9	90	28	93
	Mild	-	-	1	10	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	9	90	8	80	10	100	27	90
	Mild	1	10	2	20	-	-	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	8	80	7	70	9	90	24	80
	Mild	2	20	3	30	1	10	6	20
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	9	90	9	90	8	80	26	87

Any Assessment									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	1	10	1	10	2	20	4	13
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	8	80	9	90	27	90
	Mild	-	-	2	20	1	10	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	7	70	7	70	6	60	20	67
	Mild	3	30	3	30	4	40	10	33
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 168: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

Systolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	7	70	9	90	9	90	25	83
	Mild	3	30	1	10	1	10	5	17
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	9	90	10	100	8	80	27	90
	Mild	1	10	-	-	2	20	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	9	90	9	90	28	93
	Mild	-	-	1	10	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	9	90	9	90	10	100	28	93
	Mild	1	10	1	10	-	-	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	9	90	10	100	9	90	28	93
	Mild	1	10	-	-	1	10	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	10	100	10	100	9	90	29	97

Systolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	9	90	29	97
	Mild	-	-	-	-	1	10	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	8	80	9	90	7	70	24	80
	Mild	2	20	1	10	3	30	6	20
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 169: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

Diastolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	9	90	10	100	10	100	29	97
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	10	100	10	100	10	100	30	100

Diastolic Blood Pressure									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 170: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

Pulse Rate									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	10	100	8	80	10	100	28	93
	Mild	-	-	2	20	-	-	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	9	90	8	80	10	100	27	90
	Mild	1	10	2	20	-	-	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	9	90	10	100	29	97
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	9	90	8	80	9	90	26	87
	Mild	1	10	2	20	1	10	4	13
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	9	90	9	90	9	90	27	90

Pulse Rate									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	1	10	1	10	1	10	3	10
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	8	80	10	100	28	93
	Mild	-	-	2	20	-	-	2	7
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	8	80	8	80	8	80	24	80
	Mild	2	20	2	20	2	20	6	20
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

Table 171: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group – All Subjects ≥71 years of Age

Temperature									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	Severity	n	%	n	%	n	%	n	%
Baseline	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 8	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 15	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 29	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 36	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 43	None	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 57	None	10	100	10	100	10	100	30	100

Temperature									
		25 µg mRNA-1273 (N=10)		50 µg mRNA-1273 (N=10)		100 µg mRNA-1273 (N=10)		All Subjects (N=30)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-

Note: The “Max Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety Population.

15 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Clinically Meaningful Adverse Events

No deaths or SAEs were reported by data cutoff date.

Case narratives for participants who discontinued study vaccine administration due to an AE are provided in Section 7.3.3.1.

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16 Appendices

16.1 Study Information

- 16.1.1 Protocol and Protocol Amendments
- 16.1.2 Sample Case Report Form (Unique Pages Only)
- 16.1.3 List of IECs and IRBs (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Participant and Sample Consent Forms
- 16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Brief (One Page) Curricula Vitae or Equivalent Summaries of Training and Experience Relevant to the Performance of the Study
- 16.1.5 Signatures of Principal or Coordinating Investigator(s) and Sponsor's Responsible Medical Officer, Depending on the Regulatory Authority's Requirement, and Signature of Responsible Biostatistician
- 16.1.6 Listing of Participants Receiving Investigational Product/Investigational Product(s) From Specific Batches, Where More Than One Batch Was Used
- 16.1.7 Randomization Scheme and Codes (Participant Identification and Treatment Assigned)
- 16.1.8 Audit Certificates (if available)
- 16.1.9 Documentation of Statistical Methods
- 16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used
- 16.1.11 Publications Based on the Study
- 16.1.12 Important Publications Referenced in the Report

16.2 Participant Data Listings

- 16.2.1 Discontinued Participants
- 16.2.2 Protocol Deviations
- 16.2.3 Participants Excluded From the Efficacy Analysis
- 16.2.4 Demographic Data
- 16.2.5 Compliance or Drug Concentration Data (or both, if available)
- 16.2.6 Individual Efficacy Response Data
- 16.2.7 Adverse Event Listings (Each Participant)
- 16.2.8 Listing of Individual Laboratory Measurements by Participant, When Required by Regulatory Authorities
- 16.2.9 Vital Signs
- 16.2.10 Concomitant Medications

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16.2.11 Pregnancy Reports

16.3 Case Report Forms (CRFs)

16.3.1 CRFs for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

16.3.2 Other CRFs Submitted (only if applicable)

16.4 Individual Participant Data Listings

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