DAY 119 CSR ADDENDUM 1
(DAY 209 IMMUNOGENICITY AND SAFETY)

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 Dates:	**Original Report (Day 119 CSR):** 07 October 2020 **Report Addendum 1 (Day 209)**: 17 March 2021
Principal Investigator:	Lisa A. Jackson, MD, MPH Kaiser Permanente Washington Health Research Institute 1730 Minor Avenue, Suite 1600 Seattle, WA 98101
Date of Original (Day 119) Report:	31 Mar 2021
Date of Report (Day 209) Addendum 1:	14 Jul 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

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 (References):

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.

Doria-Rose N, Suthar MS, Makowski M, O'Connell S, McDermott AB, Flach B, et al. Antibody persistence through 6 months after the second dose of mRNA-1273 vaccine for Covid-19. N Engl J Med. 2021;Apr 6. doi: 10.1056/NEJMc2103916.

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 (Years):

Original Report (Day 119): 16 Mar 2020 (first participant first visit) to 07 Oct 2020 (data cutoff date).

Report Addendum 1 (Day 209): 16 Mar 2020 (first participant first visit) to 17 Mar 2021 (data cutoff date).

Drug Development Phase: 1

Objectives:

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
• 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 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 lipid nanoparticle (LNP)-encapsulated messenger (mRNA)-based vaccine that encodes a full-length, prefusion stabilized spike (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 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 their last vaccination. The original (Day 119) clinical study report (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 through 12; no participants were enrolled in Cohorts 6, 9, and 13. This Day 209 Immunogenicity and Safety CSR Addendum 1 (CSR Addendum 1) provides safety and immunogenicity data through Day 209 (±7 days) for Cohorts 1 through 5, 7, 8, and 10 through 12.

Number of Participants (Planned and Analyzed):

Planned: up to 155 participants

Analyzed: 120 participants

Diagnosis and Main Criteria for Inclusion and Exclusion: Refer to the Day 119 CSR for the inclusion and exclusion criteria for the study.

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

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

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

Estimands and Intercurrent Events: Not applicable**.**

Statistical Methods: Refer to the Day 119 CSR for the statistical methods for safety and immunogenicity data.

Summary of Results:

The results reported in this CSR Addendum 1 include interim analysis of safety and immunogenicity data through Day 209 (±7 days) for Cohorts 1 through 5, 7, 8, and 10 through 12.

Participant Disposition: Disposition of the participants are provided in the Day 119 CSR. No participant discontinued the study after the data cutoff date of the Day 119 CSR (07 October 2020) up to the data cutoff date of this CSR Addendum 1 (17 March 2021).

Safety Results: No safety concerns were found in the healthy adult participants aged ≥ 18 years 6 months after the second dose of mRNA-1273. A total of 32 new unsolicited AEs in 26 participants were reported in this CSR Addendum 1. This included a severe AE of parotid duct obstruction on Day 185 after the second injection in 1 participant in the 250 µg vaccination group (18 to 55 years of age group) and an SAE of renal mass 170 days after the second injection in 1 participant in the 100 µg vaccination group (≥71 years of age group). Of the 32 new unsolicited AEs, there were a total of 29 MAAEs reported in 25 participants; 5 of these MAAEs were also reported as NOCMCs. One MAAE previously reported as related to mRNA-1273 (abdominal discomfort in the 250 µg vaccination group [age group: 18 to 55 years]) in the Day 119 CSR (data cutoff of 07 October 2020) was updated to the event term of pancreatitis and the relationship was changed to not related to mRNA-1273. In addition, all new unsolicited AEs were not related to mRNA-1273. No notable trends were observed in vital sign results or physical exam findings for any age group or vaccination group, and no trend was observed among dose levels and the severity of events.

Immunogenicity Results

S-2P IgG ELISA Endpoint

- After reaching a peak level between Day 36 and Day 57, the S-2P ELISA GMT values decreased by Day 209; however the values remained numerically higher than on Day 15 (except in the 250 µg vaccination group) Notably, endpoint titers at Day 209 remained at least 4-fold higher than baseline.

- In the 18 to 55 years of age group, the S-2P ELISA GMT values on Day 209 were numerically higher in the 50 µg vaccination group compared with the other vaccination groups and were similar to the median GMT values for the convalescent sera control group. In both the 56 to 70 years and ≥71 years of age groups, the S-2P ELISA GMT values on Day 209 were numerically higher in the 100 µg vaccination groups compared with the other vaccination groups and were similar to the median GMT values for the convalescent sera control group.

S-2P RBD ELISA Endpoint

- After reaching a peak level between Day 36 and Day 43, the RBD ELISA GMT values decreased by Day 209; however, the values generally remained similar to or numerically higher than on Day 29 (except in the 50 µg and 250 µg vaccination groups in the 18 to 55 years of age group). Notably, endpoint titers at Day 209 remained at least 4-fold higher than baseline.

- In the 18 to 55 years of age group, the RBD ELISA GMT values on Day 209 were higher in the 100 µg vaccination group compared with the other vaccination groups. In both the 56 to 70 years and ≥71 years of age groups, the RBD ELISA GMT values on Day 209 were higher in the 50 µg vaccination group compared with the other vaccination groups. Compared to the convalescent sera, the RBD ELISA GMT values on Day 209 were numerically higher in all participants except in the 25 µg (all age groups) and 50 µg (18 to 55 years of age group) vaccination groups.

Pseudovirus Neutralization ID_{50} and ID_{80}

- After reaching a peak level between Day 36 and Day 57, the PsVNA GM neutralizing ID_{50} and ID_{80} values decreased by Day 209; however, in general the values remained similar to or numerically higher than on Day 29. The values were lower than the median GM values for the convalescent sera control group.

- Across all age groups, the PsVNA GM neutralizing ID_{50} and ID_{80} values on Day 209 were higher in the 100 µg vaccination group compared with the 25 µg and 50 µg vaccination groups.

FRNT-mNG

- After reaching a peak level on Day 43, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values decreased by Day 209; however, the values remained similar to or numerically higher than on Day 29 (prior to the second injection) across all age groups and dose levels.

- Across all age groups, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values on Day 209 were higher in the 100 µg vaccination group compared with the 25 µg and 50 µg vaccination groups, and were similar to or numerically higher than values for convalescent sera controls.

Conclusions: Overall, mRNA-1273, administered as 2 doses 28 days apart, was safe 6 months after the second dose in healthy adult participants aged ≥ 18 years. The immune response elicited by mRNA-1273 persisted through 6 months after the second dose with the 100 µg dose regimen eliciting higher neutralizing antibody responses compared with the 25 or 50 µg dose across all age groups and higher binding antibody responses in the 56 to 70 years and ≥71 years of age groups.

Original Report Date: 31 Mar 2021

Report Addendum Date: 14 Jul 2021

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

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 chronic medical condition
OHRP	Office for Human Research Protections
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

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

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 licensed 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 (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.

The aim of this Phase 1 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.

The original (Day 119) clinical study report (CSR) (dated 31 Mar 2021) 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 through 12; no participants were enrolled in Cohorts 6, 9, and 13. This Day 209 Immunogenicity and Safety CSR Addendum 1 (CSR Addendum 1) provides safety and immunogenicity data through Day 209 (±7 days) for Cohorts 1 through 5, 7, 8, and 10 through 12 (data cutoff date of 17 Mar 2021).

A final analysis will be performed after the final data lock 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).

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

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 chronic medical condition; S = spike; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

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 their last vaccination. This Day 209 Immunogenicity And Safety Day 119 CSR Addendum 1 (CSR Addendum 1) provides the analysis of safety and immunogenicity data through Day 209 (data cut off 17 March 2021) for Cohorts 1 through 5, 7, 8, and 10 through 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.

The Day 209 visit occurred 6 months after the second vaccination.

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 non-serious AEs were collected from the time of each vaccination through 28 days post each vaccination. The assessments are described in the Day 119 CSR.

Serious AEs, new onset chronic medical conditions (NOCMCs), and medically attended AEs (MAAEs) are being collected through the end of the study.

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).

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

Full details of the investigational plan are presented in the Day 119 CSR (Section 3).

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

The original 20-0003 Clinical Study Protocol, dated 14 Feb 2020, was amended 5 times. A summary of the major changes implemented with Versions 2.0 through Version 5.0 are described in the Day 119 CSR (Table 3). Version 6.0 of the protocol was not included or discussed in the Day 119 CSR or this CSR Addendum 1, and will be captured in a subsequent CSR for this study.

3.3 Safety Assessments

3.3.1 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 of the Day 119 CSR). 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 3.3.2). 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.

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, 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).

3.3.2 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.

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 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 3.3.1).

3.3.3 Pregnancy

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

3.3.4 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.

3.3.5 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.

3.4 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
- 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 CSR Addendum 1. 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.

3.5 Other Assessments

Other assessments are described in the Day 119 CSR (Section 3).

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

Statistical methods and sample size considerations are described in the Day 119 CSR (Section 4) and in the in 20-0003 Statistical Analysis Plan (Appendix 16.1.9).

5 Study Populations

5.1 Disposition of Participants

Disposition of the participants are provided in the Day 119 CSR (Section 5.1). No participant discontinued the study after the data cutoff date of the Day 119 CSR (07 October 2020) up to the data cutoff date of this CSR Addendum 1 (17 March 2021).

5.2 Protocol Deviations

Protocol deviations are presented in the Day 119 CSR (Section 5.2). No new major protocol deviations were reported after the data cutoff date of the Day 119 CSR (07 October 2020) up to the data cutoff date of this CSR Addendum 1 (17 March 2021).

5.3 Demographics and Other Baseline Characteristics

Demographic data are summarized in the Day 119 CSR (Section 5.3).

5.4 Exposure and Compliance

Exposure and compliance data are summarized in the Day 119 CSR (Section 5.4).

5.5 Pre-existing and Concurrent Medical Conditions

Pre-existing and concurrent medical conditions are listed by participant in the Day 119 CSR (Listing 7). No new pre-existing and concurrent medical conditions were reported after the data cutoff date of the Day 119 CSR (07 October 2020) up to the data cutoff date of this CSR Addendum 1 (17 March 2021).

5.6 Prior and Concurrent Medications

Cumulative data of prior and concurrent medications are summarized in tabular format (Posttext Table 96, Posttext Table 97, and Posttext Table 98) through Day 209 (±7 days) and the descriptions below concentrate on the new prior and concurrent medications. A cumulative listing of all prior and concurrent medications up to the data cutoff date of this CSR Addendum 1 (17 March 2021), are presented in Listing 3.

Overall, all (100%) participants in the 56 to 70 years and ≥ 71 years of age groups and 59 (98%) participants in the 18 to 55 years of age group 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 the same as were reported in the Day 119 CSR, with

the exception of vaccines, which increased substantially for each age group: from 4 (7%) participants to 21 (35%) participants in the 18-55 years of age group, from 6 (20%) participants to 20 (67%) participants in the 56-70 years of age group, and from 8 (27%) participants to 26 (87%) participant in the ≥71 years of age group. The majority of these were influenza vaccines.

6 Efficacy Results

Not applicable.

7 Safety Results

This CSR Addendum 1 includes safety results presented up to Study Day 209 (±7 days).

7.1 Solicited Adverse Reactions

Solicited adverse reactions reported within 7 days after each injection are presented in the Day 119 CSR (Section 7.1).

7.2 Unsolicited Adverse Events

Unsolicited non-serious AEs were collected from Day 1 to Day 57, and SAEs, MAAEs, and NOCMCs are being collected through the end of study.

Unsolicited AEs reported through data cutoff date of Day 119 CSR (07 October 2020, through Day 57 for Cohorts 10,11, and 12 or Day 119 for Cohorts 1 through 5, 7 and 8) are presented in the Day 119 CSR. This CSR Addendum 1 summarizes cumulative data of unsolicited AEs through Day 209 (±7 days) in tabular format and the description concentrating on the new AEs. A cumulative listing of all unsolicited AEs, SAEs, MAAEs, and NOCMCs up to the data cutoff date of this CSR Addendum 1 (17 March 2021) are presented in Listing 4.

Due to delays in data entry, some events that occurred before the data cutoff date of the Day 119 CSR (07 October 2020) were not included in the Day 119 CSR. These unsolicited AEs along with SAEs, MAAEs, and NOCMCs reported between the data cutoff date of Day 119 CSR and this CSR Addendum 1 are considered as new unsolicited AEs and the descriptions below concentrate on these new unsolicited AEs. A total of 32 new AEs in 26 participants are discussed in this CSR Addendum 1 (Posttext Table 80).

7.2.1 Overview of Unsolicited Adverse Events

Age Group: 18 to 55 Years

Table 3 presents an overall summary of unsolicited AEs through Day 209 (±7 days). The incidence of unsolicited AEs was similar among the vaccination groups. All new unsolicited AEs were not related to mRNA-1273 (Posttext Table 80). One new severe unsolicited AE (parotid duct obstruction) was reported in a participant in the 250 µg vaccination group (Section 7.2.3). No serious or fatal AEs were reported. No new AEs leading to vaccine or study discontinuation were reported.

Age Group: 56 to 70 Years

Table 4 presents an overall summary of unsolicited AEs through Day 209 (±7 days). The incidence of unsolicited AEs was similar among the vaccination groups. All new unsolicited AEs were not related to mRNA-1273 (Posttext Table 80). No serious or fatal AEs were reported. No new AEs leading to vaccine or study discontinuation were reported.

Age Group: ≥ 71 Years

Table 5 presents an overall summary of unsolicited AEs through Day 209 (±7 days). The incidence of unsolicited AEs was similar among the vaccination groups. All new unsolicited AEs were not related to mRNA-1273 (Posttext Table 80). One new SAE (renal mass) was reported in a participant in the 100 µg vaccination group (Section 7.3.2). No severe or fatal AEs or AEs leading to vaccine or study discontinuation were reported.

Table 3: Overall Summary of Unsolicited Adverse Events Through Day 209 (±7 days) (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)	11 (73)	12 (80)	12 (80)	47 (78)
Serious	–	–	–	–	–
Fatal	–	–	–	–	–
MAAE	7 (47)	4 (27)	3 (30)	7 (47)	21 (35)
NOCMC	–	–	1 (7)	1 (7)	2 (3)
Leading to discontinuation from study vaccine	1 (7)	–	–	1 (7)	2 (3)
Leading to discontinuation from study	–	–	–	–	–
Severe	–	–	–	2 (13)	2 (3)
Unsolicited AEs related to study vaccine, n (%)					
All	4 (27)	6 (40)	3 (20)	7 (47)	20 (33)
Serious	–	–	–	–	–
Fatal	–	–	–	–	–
MAAE	–	–	–	–	–
NOCMC	–	–	–	–	–
Leading to discontinuation from study vaccine	1 (7)	–	–	–	1 (2)
Leading to discontinuation from study	–	–	–	–	–
Severe	–	–	–	–	–

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 76.

Table 4: Overall Summary of Unsolicited Adverse Events Through Day 209 (±7 days) (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	8 (80)	7 (70)	8 (80)	23 (77)
Serious	–	–	–	–
Fatal	–	–	–	–
MAAE	2 (20)	6 (60)	1 (10)	9 (30)
NOCMC	1 (10)	2 (20)	–	3 (10)
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 77.

Table 5: Overall Summary of Unsolicited Adverse Events Through Day 209 (±7 days) (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)	7 (70)	9 (90)	25 (83)
Serious	–	–	1 (10)	1 (3)
Fatal	–	–	–	–
MAAE	2 (20)	3 (30)	5 (50)	10 (33)
NOCMC	–	1 (10)	1 (10)	2 (7)
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 78.

7.2.2 Most Common Unsolicited Adverse Events

Age Group: 18 to 55 Years

As of data cutoff for this CSR Addendum 1, a total of 47 (78%) participants reported 138 unsolicited AEs (Table 6). Twelve participants reported 15 new unsolicited AEs in the 18 to 55 years of age group: 3 participants (3 AEs) in the 25 µg vaccination group, 3 participants (6 AEs) in the 50 µg vaccination group, 1 participant (1 AE) in the 100 µg vaccination group, and 5 participants (5 AEs) in the 250 µg vaccination group.

Based on the unsolicited AEs reported through Day 209 (±7 days) including the new AEs, the most commonly reported unsolicited AEs remained the same as reported in the Day 119 CSR. 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 Addendum 1, 23 (77%) participants reported 40 unsolicited AEs. (Table 7). Six participants reported 8 new unsolicited AEs in the 56 to 70 years of age group: 2 participants (4 AEs) in the 25 µg vaccination group, 3 participants (3 AEs) in the 50 µg vaccination group, 1 participant (1 AE) in the 100 µg vaccination group.

Based on the unsolicited AEs reported through Day 209 (±7 days) including the new AEs, the most commonly reported unsolicited AEs remained the same as reported in the Day 119 CSR. 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 Addendum 1, 25 (83%) participants reported 68 unsolicited AEs (Table 8). Eight participants reported 9 new unsolicited AEs in the ≥ 71 years of age group: 2 participants (2 AEs) in the 25 µg vaccination group, 3 participants (4 AEs) in the 50 µg vaccination group, 3 participants (3 AE) in the 100 µg vaccination group.

Based on the unsolicited AEs reported through Day 209 (±7 days) including the new AEs, the most commonly reported unsolicited AEs remained the same as reported in the Day 119 CSR. Although 9 new AEs were reported, the total number of unsolicited AEs were still lower in the 50 µg vaccination group than in the 25 µg and 100 µg vaccination groups.

Table 6: Number and Percentage of Participants Reporting Unsolicited Adverse Events Through Day 209 (±7 days) (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	34	30	29	45	138
Participants with any unsolicited AE, n (%)	12 (80)	11 (73)	12 (80)	12 (80)	47 (78)
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)	4 (27)	2 (13)	7 (47)	17 (28)
Abdominal discomfort	–	–	1 (7)	–	1 (2)
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)
Gastritis	–	–	–	1 (7)	1 (2)
Inguinal hernia	–	1 (7)	–	–	1 (2)
Feces discolored	–	–	1 (7)	–	1 (2)
Flatulence	1 (7)	–	–	–	1 (2)
Lip disorder	–	–	–	1 (7)	1 (2)
Pancreatitis	–	–	–	1 (7)	1 (2)
Parotid duct obstruction				1 (7)	1 (2)
Tooth impacted	–	1 (7)	–	–	1 (2)
Vomiting	3 (20)	–	–	1 (7)	4 (7)

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)	2 (13)	2 (13)	2 (13)	8 (13)
Bacterial vaginosis	–	–	–	1 (7)	1 (2)
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)
Respiratory tract infection	–	1 (7)	–	–	1 (2)
Upper respiratory tract infection	–	1 (7)	–	–	1 (2)
Urinary tract infection	–	–	–	1 (7)	1 (2)
Injury, poisoning and procedural complications	6 (40)	3 (20)	3 (20)	1 (7)	13 (22)
Contusion	3 (20)	1 (7)	–	–	4 (7)
Limb injury	1 (7)	–	–	–	1 (2)
Muscle strain	2 (13)	–	2 (13)	–	4 (7)
Skin abrasion	1 (7)	2 (13)	–	–	3 (5)
Skin injury	–	–	–	1 (7)	1 (2)
Skin laceration	1 (7)	–	–	–	1 (2)
Thermal burn	–	–	1 (7)	–	1 (2)
Wound	1 (7)	–	–	–	1 (2)
Investigations	–	1 (7)	1 (7)	–	2 (3)

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)
Blood glucose decreased	–	1 (7)	–	–	1 (2)
Heart rate increased	–	–	1 (7)	–	1 (2)
Metabolism and nutrition disorders	1 (7)	–	1 (7)	4 (27)	6 (10)
Decreased appetite	–	–	1 (7)	3 (20)	4 (7)
Hypoglycemia	–	–	–	1 (7)	1 (2)
Iron deficiency	1 (7)	–	–	–	1 (2)
Musculoskeletal and connective tissue disorders	2 (13)	3 (20)	1 (7)	4 (27)	10 (17)
Arthralgia	–	1 (7)	–	1 (7)	2 (3)
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 (7)	2 (3)
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	–	–	2 (13)	2 (13)	4 (7)
Anxiety	–		1 (7)	1 (7)	2 (3)
Attention deficit hyperactivity disorder	–	–	1 (7)	–	1 (2)
Bipolar II disorder	–	–	–	1 (7)	1 (2)
Insomnia	–	–	–	1 (7)	1 (2)
Reproductive system and breast disorders	–	1 (7)	1 (7)	3 (20)	5 (8)
Breast pain	–	–	1 (7)	–	1 (2)
Dysfunctional uterine bleeding	–	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)

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)
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)
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)
Photosensitivity reaction	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 50, Posttext Table 51, Posttext Table 52, Posttext Table 53, Posttext Table 54, Posttext Table 63, Posttext Table 64, Posttext Table 65, Posttext Table 66, and Posttext Table 67

Table 7: Number and Percentage of Participants Reporting Unsolicited Adverse Events Through Day 209 (±7 days) (All Participants 56 to 70 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	17	11	12	40
Participants with any unsolicited AE, n (%)	8 (80)	7 (70)	8 (80)	23 (77)
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	–	2 (20)	1 (10)	3 (10)
Abdominal discomfort	–	1 (10)	–	1 (3)
Gastrooesophageal reflux disease	–	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)	3 (30)	1 (10)	5 (17)
Onychomycosis	1 (10)	–	–	1 (3)
Paronychia	–	–	1 (10)	1 (3)
Urinary tract infection	–	1 (10)	–	1 (3)
Viral infection	–	2 (20)	–	2 (7)
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	2 (20)	–	1 (10)	3 (10)
Decreased appetite	1 (10)	–	–	1 (3)
Glucose tolerance impaired	1 (10)	–	–	1 (3)
Hypoglycemia	–	–	1 (10)	1 (3)
Musculoskeletal and connective tissue disorders	1 (10)	1 (10)	–	2 (7)
Osteoporosis	–	1 (10)	–	1 (3)

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)
Pain in extremity	1 (10)	–	–	1 (3)
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 (10)	2 (7)
Diastolic hypertension	1 (10)	–	–	1 (3)
Systolic hypertension	1 (10)	–	1 (10)	2 (7)

Abbreviation: AE = adverse event.

A participant was counted once per preferred term.

Sources: Posttext Table 55, Posttext Table 56, Posttext Table 57, Posttext Table 58, Posttext Table 68, Posttext Table 69, Posttext Table 70, and Posttext Table 71.

Table 8: Number and Percentage of Participants Reporting Unsolicited Adverse Events Through Day 209 (±7 days) (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	30	11	27	68
Participants with any unsolicited AE, n (%)	9 (90)	7 (70)	9 (90)	25 (83)
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)	1 (10)	3 (10)
Cellulitis	–	1 (10)	–	1 (3)
Pustule	1 (10)	–	–	1 (3)
Urinary tract infection	–	–	1 (10)	1 (3)
Injury, poisoning and procedural complications	5 (50)	2 (20)	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)
Metabolism and nutrition disorder	–	–	1 (10)	1 (3)
Hypercholesterolaemia	–	–	1 (10)	1 (3)
Musculoskeletal and connective tissue disorders	4 (40)	1 (10)	1 (10)	6 (20)
Arthritis	1 (10)	–	–	1 (3)
Joint swelling	1 (10)	–	–	1 (3)
Medial tibial stress syndrome	1 (10)	–	–	1 (3)
Muscle tightness	1 (10)	–	–	1 (3)

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)
Musculoskeletal chest pain	1 (10)	–	–	1 (3)
Myalgia	–	–	1 (10)	1 (3)
Osteoarthritis	–	1 (10)	–	1 (3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	–	–	1 (10)	1 (3)
Malignant melanoma	–	–	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)	1 (10)	–	3 (10)
Depression	–	1 (10)	–	1 (3)
Anxiety	1 (10)	–	–	1 (3)
Sleep disorder	1 (10)	–	–	1 (3)
Renal and urinary disorders	–	–	1 (10)	1 (3)
Renal mass	–	–	1 (10)	1 (3)
Reproductive system and breast disorders	–	1 (10)	–	1 (3)
Benign prostatic hyperplasia	–	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)
Actinic keratosis	1 (10)	–	–	1 (3)
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 (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 59, Posttext Table 60, Posttext Table 61, Posttext Table 62, Posttext Table 72, Posttext Table 73, Posttext Table 74, and Posttext Table 75.

7.2.3 Unsolicited Adverse Events by Maximum Intensity

Age Group: 18 to 55 Years

Of 138 unsolicited AEs reported through Day 209, all AEs were mild or moderate in intensity except 3 severe unsolicited AEs in 2 participants (Table 9). Of these, 2 severe AEs in 1 participant were reported before Day 119 and provided in the Day 119 CSR Section 7.2.3.

One participant in the 250 µg vaccination group reported a new severe unsolicited AE of parotid duct obstruction on Day 185 after the second injection. The event was ongoing at the time of data cutoff of this CSR Addendum 1 and not related to mRNA-1273.

Age Group: 56 to 70 Years

Of 40 unsolicited AEs reported through Day 209, all AEs were mild or moderate in intensity except 2 severe unsolicited AEs in 2 participants (Table 10). The details about these 2 severe AEs are provided in the Day 119 CSR Section 7.2.3.

Age Group: ≥ 71 Years

All 68 unsolicited AEs reported through Day 209 were mild or moderate in intensity (Table 11). The only SAE reported in the study (in the 100 µg vaccination group) was moderate in severity (Section 7.3.2).

Table 9: Summary of Unsolicited Adverse Events by Severity Through Day 209 (±7 days) (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	34	30	29	45	138
Mild	30	22	22	25	99
Moderate	4	8	7	17	36
Severe	–	–	–	3	3
Participants with any unsolicited AE, n (%)	12 (80)	11 (73)	12 (80)	12 (80)	47 (78)
Mild	12 (80)	10 (67)	9 (60)	7 (47)	38 (63)
Moderate	4 (27)	4 (27)	6 (40)	10 (67)	24 (40)
Severe	–	–	–	2 (13)	2 (3)

Abbreviation: AE = adverse event.

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

Sources: Posttext Table 50, Posttext Table 51, Posttext Table 52, Posttext Table 53, Posttext Table 54, Posttext Table 63, Posttext Table 64, Posttext Table 65, Posttext Table 66, and Posttext Table 67.

Table 10: Summary of Unsolicited Adverse Events by Severity Through Day 209 (±7 days) (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	17	11	12	40
Mild	11	5	6	22
Moderate	6	5	5	16
Severe		1	1	2
Participants with any unsolicited AE, n (%)	8 (80)	7 (70)	8 (80)	23 (77)
Mild	7 (70)	5 (50)	5 (50)	17 (57)
Moderate	4 (40)	5 (50)	2 (20)	11 (37)
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 55, Posttext Table 56, Posttext Table 57, Posttext Table 58, Posttext Table 68, Posttext Table 69, Posttext Table 70, and Posttext Table 71.

Table 11: Summary of Unsolicited Adverse Events by Severity Through Day 209 (±7 days) (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	30	11	27	68
Mild	27	8	26	61
Moderate	3	3	1	7
Severe	–	–	–	–
Participants with any unsolicited AE, n (%)	9 (90)	7 (70)	9 (90)	25 (83)
Mild	9 (90)	7 (70)	8 (80)	24 (80)
Moderate	2 (20)	2 (20)	1 (10)	5 (17)
Severe	–	–	–	–

Abbreviation: AE = adverse event.

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

Sources: Posttext Table 59, Posttext Table 60, Posttext Table 61, Posttext Table 62, Posttext Table 72, Posttext Table 73, Posttext Table 74, and Posttext Table 75.

7.2.4 Unsolicited Adverse Events by Relationship to Investigational Product

A summary of unsolicited AEs by relationship to mRNA-1273 through Day 209 (±7 days) is provided in Table 12, Table 13, and Table 14.

All new unsolicited AEs were not related to mRNA-1273 (Posttext Table 80).

Details about previously reported unsolicited AEs related to mRNA-1273 are provided in the Day 119 CSR (Section 7.2.4).

The Day 119 CSR included an MAAE of abdominal discomfort in the 250 µg vaccination group (age group: 18 to 55 years) deemed related to mRNA-1273; however, after the data cutoff for the Day 119 CSR (07 October 2020), the event term was updated to pancreatitis and the relationship was updated to not related to mRNA-1273 (Listing 4).

Table 12: Summary of Unsolicited Adverse Events by Relationship Through Day 209 (±7 days) (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	34	30	29	45	138
Not related	29	23	19	27	98
Related	5	7	10	18	40
Participants with any unsolicited AE, n (%)	12 (80)	11 (73)	12 (80)	12 (80)	47 (78)
Not related	12 (80)	9 (60)	10 (67)	10 (67)	41 (68)
Related	4 (27)	6 (40)	3 (20)	7 (47)	20 (33)

Abbreviations: AE = adverse event.

Sources: Posttext Table 50, Posttext Table 51, Posttext Table 52, Posttext Table 53, Posttext Table 54, Posttext Table 63, Posttext Table 64, Posttext Table 65, Posttext Table 66, and Posttext Table 67.

Table 13: Summary of Unsolicited Adverse Events by Relationship Through Day 209 (±7 days) (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	17	11	12	40
Not related	15	10	11	36
Related	2	1	1	4
Participants with any unsolicited AE, n (%)	8 (80)	7 (70)	8 (80)	23 (77)
Not related	6 (60)	7 (70)	8 (80)	21 (70)
Related	2 (20)	1 (10)	1 (10)	4 (13)

Abbreviations: AE = adverse event.

Sources: Posttext Table 55, Posttext Table 56, Posttext Table 57, Posttext Table 58, Posttext Table 68, Posttext Table 69, Posttext Table 70, and Posttext Table 71.

Table 14: Summary of Unsolicited Adverse Events by Relationship Through Day 209 (±7 days) (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	30	11	27	68
Not related	19	11	24	54
Related	11	–	3	14
Participants with any unsolicited AE, n (%)	9 (90)	7 (70)	9 (90)	25 (83)
Not related	7 (70)	7 (70)	8 (80)	22 (73)
Related	4 (40)	–	3 (30)	7 (23)

Abbreviations: AE = adverse event.

Sources: Posttext Table 59, Posttext Table 60, Posttext Table 61, Posttext Table 62, Posttext Table 72, Posttext Table 73, Posttext Table 74, and Posttext Table 75.

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 Addendum 1, no deaths had occurred during the study.

7.3.2 Other Serious Adverse Events

At the time of the data cutoff for this CSR, one SAE had been reported during the study (Posttext Table 79).

One participant (100 µg vaccination group, ≥71 years of age group) experienced a moderate SAE of renal mass 170 days after the second injection. The event was not related to mRNA-1273 and resolved within 22 days.

A 73-year-old male was assigned to the 100 µg of mRNA-1273 vaccination group. The participant received the first dose on 12 May 2020 and the second dose on 08 June 2020. The participant's medical history included gastroesophageal reflux disease, left shoulder bursitis, and hyperlipidemia. On 24 November 2020, the participant had acute onset of right flank pain and blood in the urine. On 25 November 2020, computerized tomography of the abdomen showed a 6.5 cm right renal mass. Relevant laboratory tests on 25 November 2020 included blood creatinine level of 1.38 mg/dL (normal range: 0.50 to 1.30), glomerular filtration rate of 51

mL/min/1.73m^2 (normal range: 60 to 100), neutrophil count of 7.4 K/mcL (normal range: 2.00 to 7.30), and lymphocyte count of 0.7 K/mcL (normal range: 1.00 to 3.40). On 16 December 2020, the participant was hospitalized for right laparoscopic radical nephrectomy. On 17 December 2020, the laboratory tests included white blood cell count (WBC) of 10.2, hemoglobin (HGB) of 11.5, hematocrit of 35.1, platelet count of 157, sodium of 137, potassium of 4.2, chloride of 104, carbon dioxide of 26, blood urea nitrogen (BUN) of 13 and calcium of 8.0 (normal ranges and units not provided). Concomitant medications included acetaminophen 650 mg as needed (30 June 2020-ongoing) for shoulder bursitis, calcium carbonate 1 tablet as needed (05 July 2020-ongoing) for GERD, Vitamin D3 1 capsule weekly (01 November 2020-ongoing) for health maintenance, and calcium 1200 mg orally as needed. On 17 December 2020, the participant received an official diagnosis of clear cell renal cell carcinoma; therefore, the SAE of renal mass was updated to "resolved." The updated SAE diagnosis of clear cell renal cell carcinoma was entered into the database after the data cutoff for the CSR Addendum 1 (17 March 2021) and as such is not included in the CSR Addendum 1. The participant was discharged from the hospital on 17 December 2020. The investigator assessed the event of renal mass to be not related to mRNA-1273.

7.3.3 Other Clinically Meaningful Adverse Events

7.3.3.1 Adverse Events Leading to Discontinuation

Adverse events leading to discontinuation from the vaccine are provided in the Day 119 CSR (Section 7.3.3.1). As of data cutoff date of this CSR Addendum 1, there were no new AEs leading to discontinuation.

7.3.3.2 Adverse Events of Special Interest

As of the database cutoff for this CSR Addendum 1, a total of 29 new MAAEs were reported in 25 participants; 5 of these events were also reported as NOCMCs. Most of the events resolved or were resolving at the time of data cut off of this CSR Addendum 1; however, 6 events did not resolve (Posttext Table 80).

The Day 119 CSR included an MAAE of abdominal discomfort in the 250 µg vaccination group (age group: 18 to 55 years) deemed related to mRNA-1273; however, after the data cutoff for the Day 119 CSR (07 October 2020), the event term was updated to pancreatitis and the relationship was updated to not related to mRNA-1273 (Listing 4). Notably, the cumulative data of all MAAEs or NOCMCs up to the data cutoff date of this CSR Addendum 1 (17 March 2021) show that none of these events were considered related to mRNA-1273 (Table 3, Table 4, and Table 5).

7.4 Clinical Laboratory Evaluation

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). The results are presented in the Day 119 CSR (Section 7.4).

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

7.5.1 Vital Signs

This CSR Addendum 1 summarizes cumulative data of vital signs by assessment, maximum severity, time point, and vaccination group in tabular format (Posttext Table 81, Posttext Table 82, Posttext Table 83, Posttext Table 84, Posttext Table 85, Posttext Table 86, Posttext Table 87, Posttext Table 88, Posttext Table 89, Posttext Table 90, Posttext Table 91, Posttext Table 92, Posttext Table 93, Posttext Table 94, and Posttext Table 95) through Day 209 (±7 days). In addition, a cumulative listing of vital signs measurements through Day 209 (±7 days) is presented by participant in Listing 1.

Overall, no notable trends were observed in vital sign results for any age group or vaccination group, and no trend was observed among age group or vaccination group and the severity of events for any parameter.

Most of the abnormalities at the Day 209 visit were mild. Three participants had moderate vital sign abnormalities at Day 209: 1 participant in the 18 to 55 years of age group (50 µg vaccination group) had a pulse rate of 48 bpm; 1 participant in the 56-70 years of age group (25 µg vaccination group) had a diastolic blood pressure of 96 mm Hg; and 1 participant in the ≥71 years of age group (100 µg vaccination group) had a diastolic blood pressure of 99 mm Hg. One participant in the ≥71 years of age group (50 µg vaccination group) had abnormal systolic blood pressure of 166 mm Hg on Day 209 that was considered severe.

7.5.1.1 Vital Signs Reported as Adverse Events

Abnormal vital sign measurements captured as unsolicited AEs that were not included in the Day 119 CSR due to data entry delay were reported for 1 participant in the 56 to 70 years of age group (25 µg vaccination group). This participant had systolic hypertension on Day 7 after the first injection that resolved after 8 days. This same participant had systolic and diastolic hypertension on Day 28 after the first injection. The diastolic hypertension resolved after 9 days and the systolic hypertension was ongoing at the time of the CSR Addendum 1 data cutoff.

7.5.2 Physical Examination

A cumulative listing of physical examination findings through Day 209 (±7 days) is presented by participant in Listing 2.

One new abnormal physical examination findings related to the skin system was reported in 1 participant in the ≥ 71 years of age group (25 µg vaccination group) at Day 209 that was not captured as an AE.

7.6 Pregnancies

As of the data cutoff for this CSR Addendum 1, no pregnancies have been reported.

8 Immunogenicity Results

The Day 119 CSR presents immunogenicity assessments through Day 57 (Cohorts 10 through 12) or Day 119 (Cohorts 1 to 5, 7, and 8) and included results of ELISA to quantify the binding antibody IgG responses to full-length S-2P protein and to the RBD, SARS-CoV-2 native S--bearing PsVNA, live-virus neutralization assessments, FRNT-mNG, and a SARS-CoV-2 PRNT (wild-type SARS-CoV-2 virus), and an intracellular cytokine stimulation to evaluate T-cell responses.

This CSR Addendum 1 presents immunogenicity assessments through Day 209 (6 months after the second vaccination) for Cohorts 1 to 5, 7, 8, and 10 through 12, and includes results of SARS-CoV-2 S-2P– and RBD–specific binding antibody by ELISA, and pseudovirus neutralization and live-virus FRNT-mNG assays.

Prior to the data cutoff for the Day 119 CSR, one baseline RBD data point in the 18 to 55 years of age group (50 µg vaccination group) was noted as missing. The sample was rerun, and the updated RBD data were included in the Day 119 CSR. This same baseline sample was also rerun for S-2P; however, because the S-2P data point had not been noted as missing, the updated values for this assay were not included prior to finalization of the Day 119 CSR. The updated S-2P data have subsequently been reported in this CSR Addendum 1. This has resulted in a minor difference in the S-2P serum IgG ELISA GMT and corresponding S-2P serum IgG ELISA GMT GMFR reported in this addendum as compared to the Day 119 CSR.

A cumulative listing of immunogenicity assay results through Day 209 is presented by participant in Listing 5.

8.1 IgG ELISA

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

As shown in Figure 1, after reaching a peak level between Day 36 and Day 57, the S-2P ELISA GMT values decreased by Day 209.

In the 18 to 55 years of age group, the 50 µg vaccination group had S-2P ELISA GMT values on Day 209 that were numerically higher compared with the other vaccination groups and were similar to the median GMT values for the convalescent sera control group (Posttext Table 1).

In both the 56 to 70 years and ≥71 years of age groups, the 100 µg vaccination groups had S-2P ELISA GMT values on Day 209 that were numerically higher compared with the other

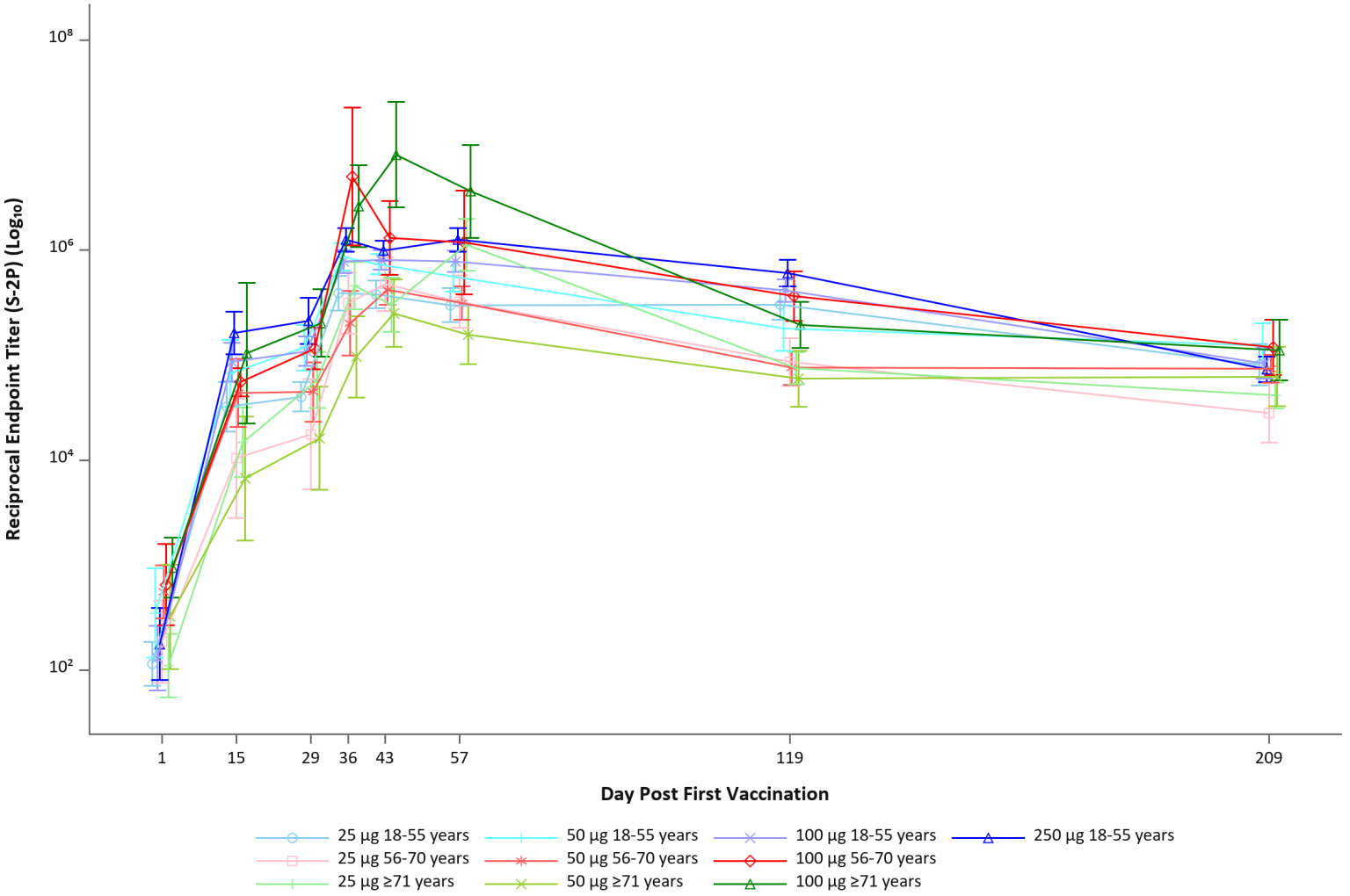
vaccination groups and were similar to the median GMT values for the convalescent sera control group (Posttext Table 2 and Posttext Table 3).

In the 18 to 55 years of age group, except for the 250 µg vaccination group, the S-2P ELISA GMT values on Day 209 remained similar to or numerically higher than values observed on Day 29 (prior to the second injection). In the 250 µg vaccination group, the S-2P ELISA GMT values on Day 209 were lower than values observed on Day 15 (14 days after the first injection).

In the 55 to 70 years of age group (all vaccination groups) and ≥71 years of age group (50 µg vaccination group only), the S-2P ELISA GMT values on Day 209 remained numerically higher than the values on Day 29 (prior to the second injection); the S-2P ELISA GMT values in the 25 and 100 µg vaccination groups in the ≥71 years of age group remained numerically higher than the values observed on Day 15 (14 days after the first injection).

Endpoint titers at Day 209 remained at least 4-fold higher than baseline (Posttext Table 25, Posttext Table 26, and Posttext Table 27).

Figure 1: 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 11.

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

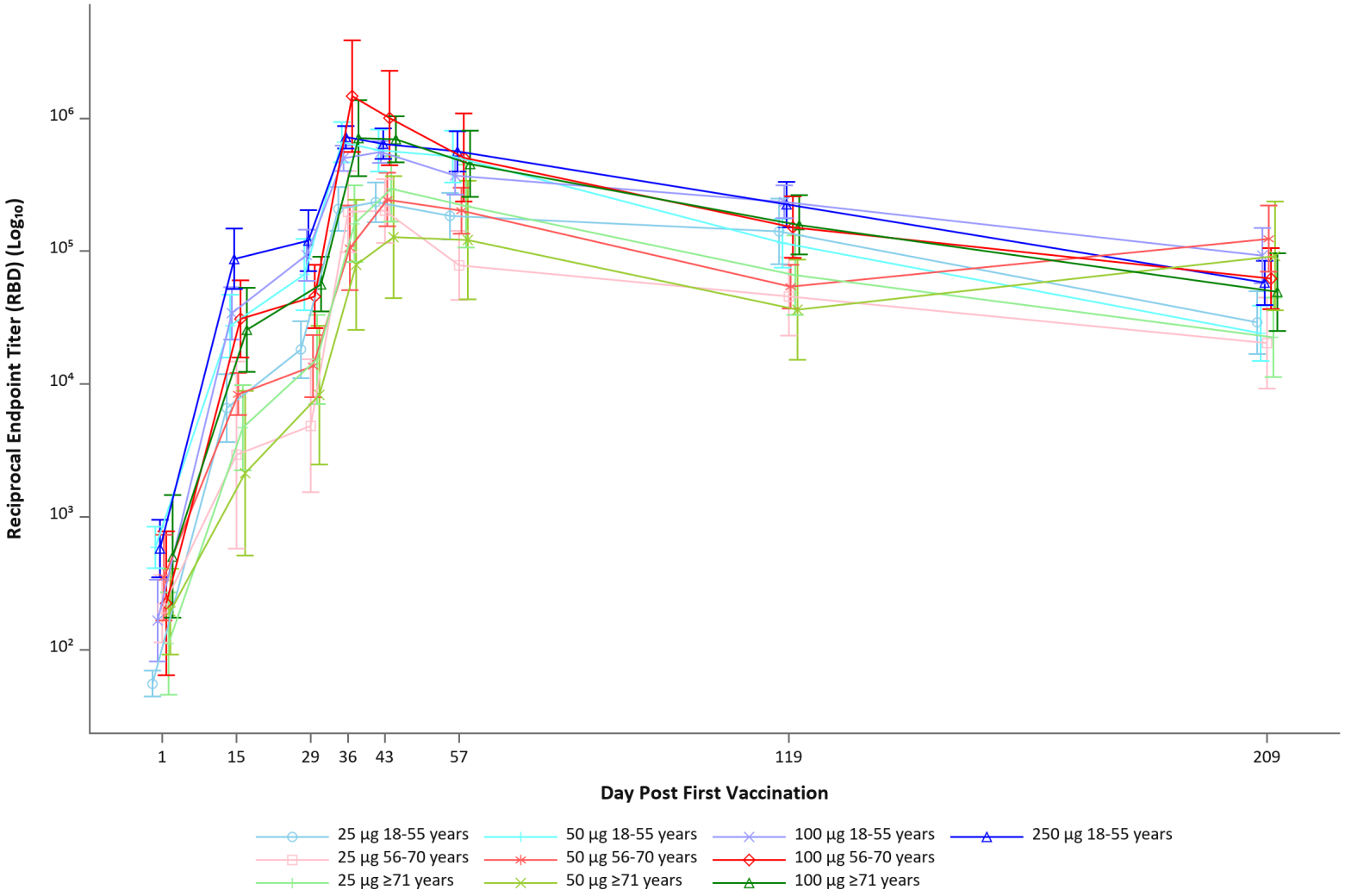
As shown in Figure 2, after reaching a peak level between Day 36 and Day 43, the RBD ELISA GMT values decreased by Day 209 except for the 50 µg vaccination group in the 56 to 70 years and ≥71 years of age groups, where the RBD ELISA GMT values decreased by Day 119 but then increased by Day 209. This observation in the 50 µg vaccination group from Day 119 to Day 209 is unlikely an actual increase in the RBD ELISA GMT values at Day 209, but rather may be because the titers reached a plateau and, due to an artifact of noise in the ELISA assay readout, appears as a rise in endpoint titers. The ELISA assay can be easily impacted by external factors and a variance in raw signal response may be at risk of being magnified.

In the 18 to 55 years of age group, the RBD ELISA GMT values on Day 209 were higher in the 100 µg vaccination group compared with the other vaccination groups (Posttext Table 4). In both the 56 to 70 years and ≥71 years of age groups, the RBD ELISA GMT values on Day 209 were higher in the 50 µg vaccination group compared with the other vaccination groups (Posttext Table 5 and Posttext Table 6).

In the 18 to 55 years of age groups, the RBD ELISA GMT values on Day 209 remained similar to or numerically higher than those on Day 29 (prior to the second injection) in the 25 and 100 µg vaccination groups but were numerically lower in the 50 and 250 µg vaccination groups. In the 56 to 70 years and ≥71 years of age group the RBD ELISA GMT values on Day 209 generally remained numerically higher than those on Day 29 (prior to the second injection). Compared to the convalescent sera, the RBD ELISA GMT values on Day 209 were numerically higher in all participants except in the 25 µg (all age groups) and 50 µg (18 to 55 years of age group) vaccination groups.

Endpoint titers at Day 209 remained at least 4-fold higher than baseline (Posttext Table 28, Posttext Table 29, Posttext Table 30).

Figure 2: Geometric Mean Endpoint Titer Values by Time Point and Vaccination Group – RBD



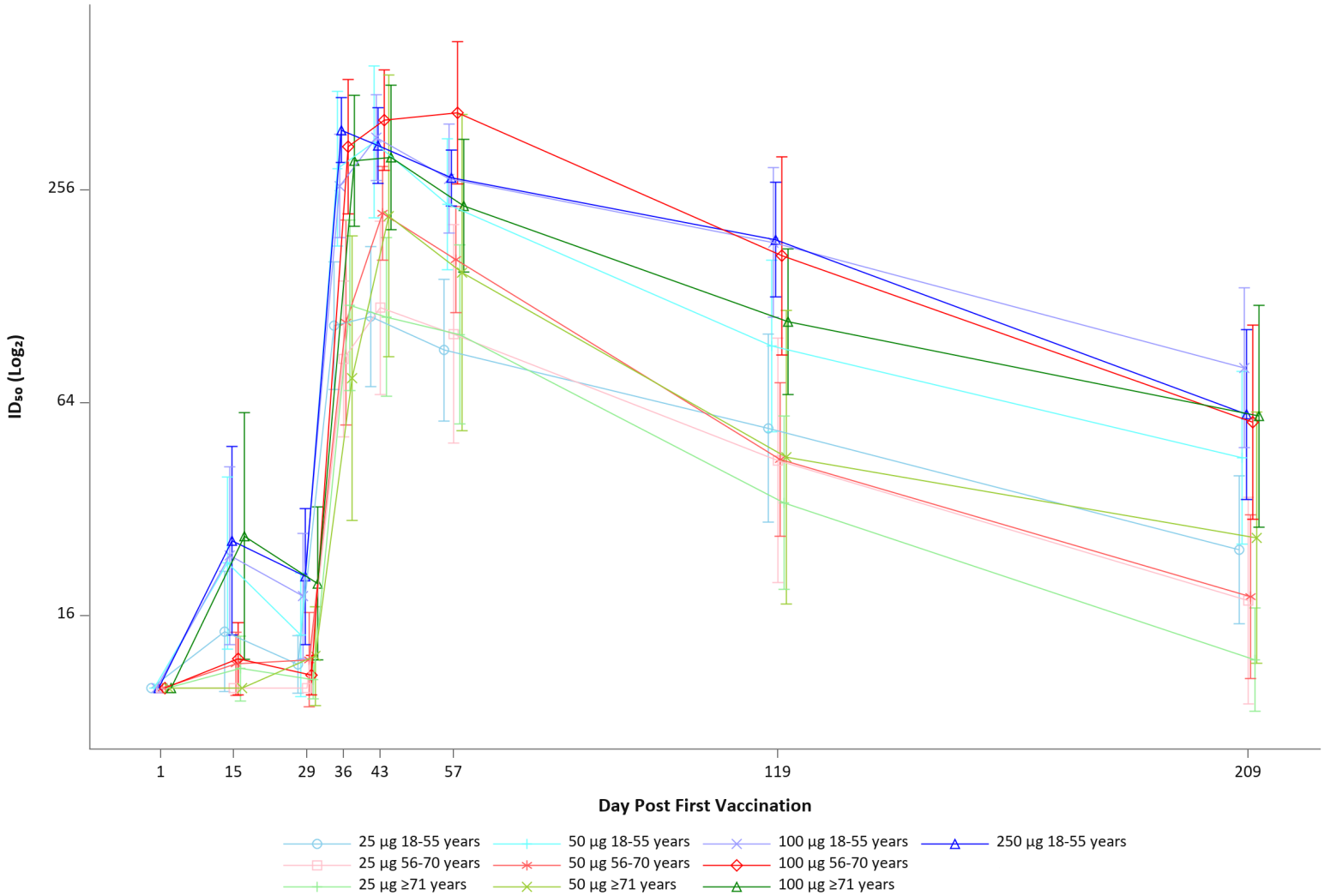
Abbreviation: S-2P = spike protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein into a prefusion conformation.
Source: Posttext Figure 12.

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

After reaching a peak level between Day 36 and Day 57, the PsVNA GM neutralizing ID_{50} (Figure 3) and ID_{80} (Figure 4) values decreased by Day 209.

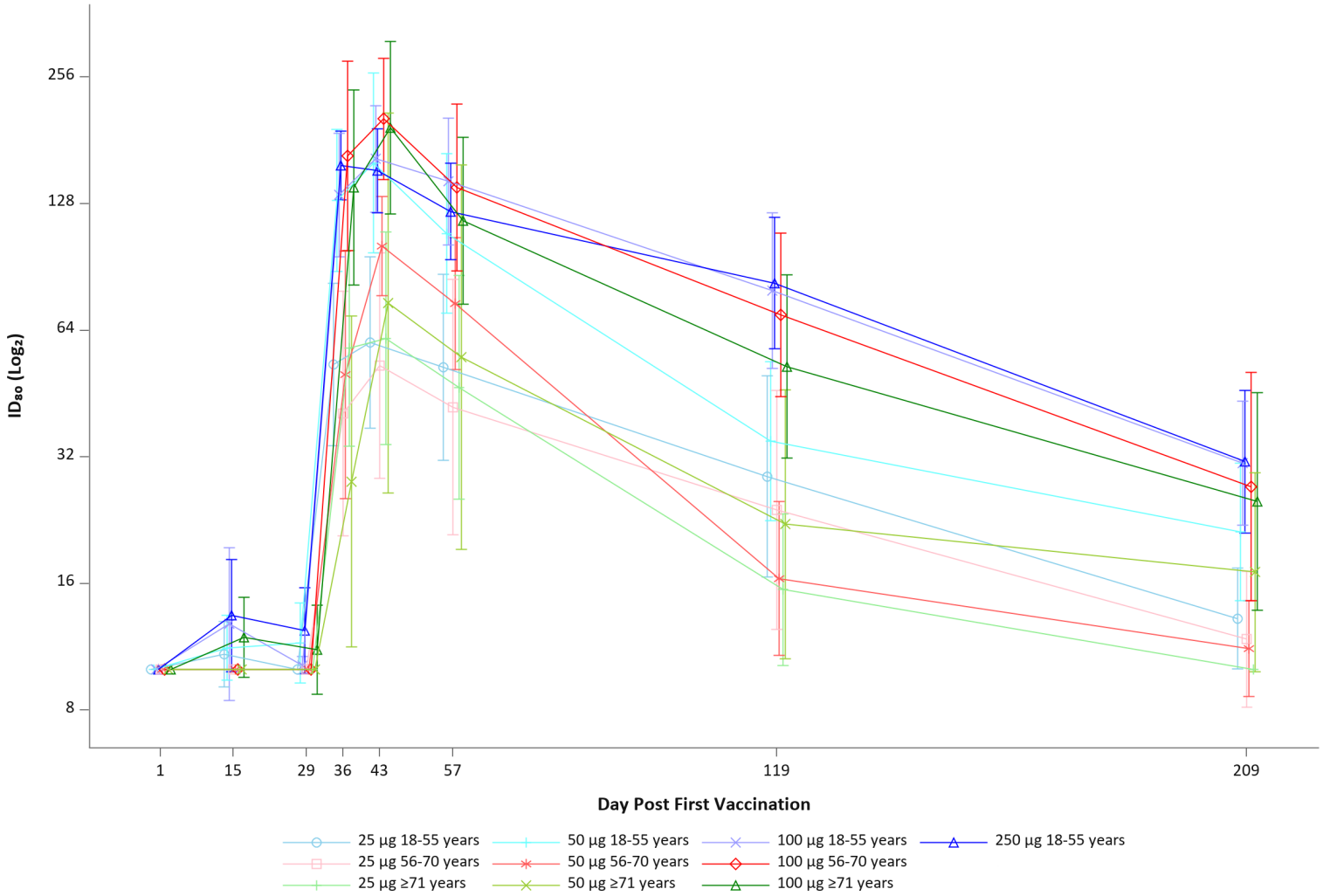
Across all age groups, the PsVNA GM neutralizing ID_{50} and ID_{80} values on Day 209 were higher in the 100 µg vaccination group compared with the 25 µg and 50 µg vaccination groups (PsVNA ID_{50}: Posttext Table 13, Posttext Table 14, Posttext Table 15; PsVNA ID_{80}: Posttext Table 16, Posttext Table 17, Posttext Table 18). For all age groups and dose levels, PsVNA GM neutralizing ID_{50} and ID_{80} values on Day 209 remained similar to or numerically higher than Day 29 (prior to the second injection) values; however, the values were lower than the median GM values for the convalescent sera control group.

Figure 3: 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 15.

Figure 4: 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 16.

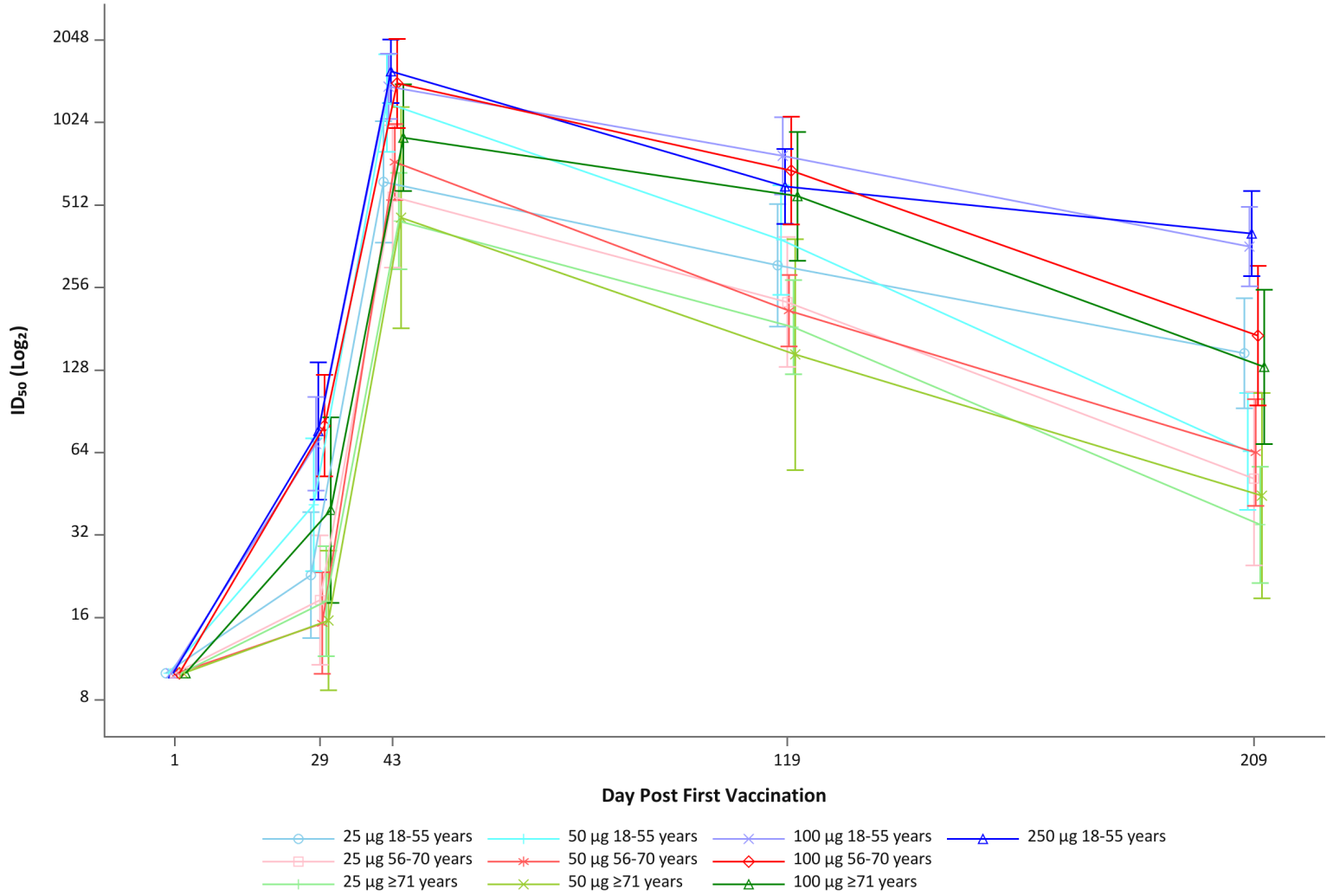
8.3 SARS-CoV-2 Live-Virus Focus-Reduction Neutralization Test Using mNeon Green (FRNT-mNG)

After reaching a peak level on Day 43, the FRNT-mNG GM neutralizing ID_{50} (Figure 5) and ID_{80} (Figure 6) values, decreased by Day 209.

Across all age groups, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values on Day 209 were the numerically higher in the 100 µg vaccination group compared with the 25 and 50 µg vaccination groups (FRNT-mNG ID_{50}: Posttext Table 19, Posttext Table 20, and Posttext Table 21; FRNT-mNG ID_{80}: Posttext Table 22, Posttext Table 23, and Posttext Table 24).

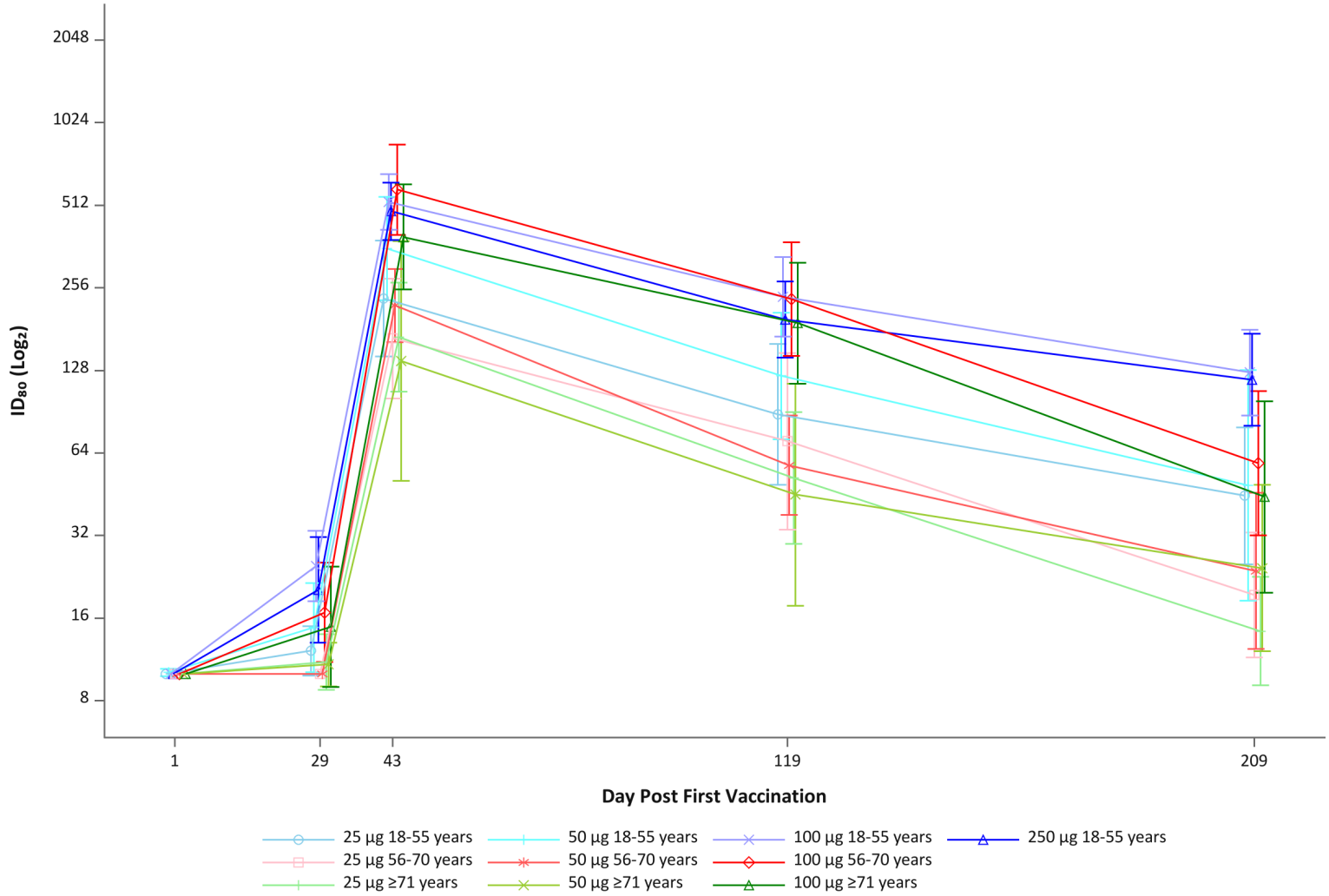
For all age groups and dose levels, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values on Day 209 remained similar to or numerically higher than values on Day 29 (prior to the second injection). Across all age groups, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values at Day 209 for 100 µg and 250 µg vaccination groups were similar to or numerically higher than the median GM values for the convalescent sera control group.

Figure 5: 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 17.

Figure 6: 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 18.

9 Conclusions

Safety

No safety concerns were found in the healthy adult participants aged ≥ 18 years 6 months after the second dose of mRNA-1273. A total of 32 new unsolicited AEs in 26 participants were reported in this CSR Addendum 1. This included a severe AE of parotid duct obstruction on Day 185 after the second injection in 1 participant in the 250 µg vaccination group (18 to 55 years of age group) and an SAE of renal mass 170 days after the second injection in 1 participant in the 100 µg vaccination group (≥71 years of age group). Of the 32 new unsolicited AEs, there were a total of 29 MAAEs reported in 25 participants; 5 of these MAAEs were also reported as NOCMCs. One MAAE previously reported as related to mRNA-1273 (abdominal discomfort in the 250 µg vaccination group [age group: 18 to 55 years]) in the Day 119 CSR (data cutoff of 07 October 2020) was updated to the event term of pancreatitis and the relationship was changed to not related to mRNA-1273. In addition, all new unsolicited AEs were not related to mRNA-1273. No notable trends were observed in vital sign results or physical exam findings for any age group or vaccination group, and no trend was observed among dose levels and the severity of events.

Immunogenicity

S-2P IgG ELISA Endpoint

- After reaching a peak level between Day 36 and Day 57, the S-2P ELISA GMT values decreased by Day 209; however the values remained numerically higher than on Day 15 (except in the 250 µg vaccination group). Notably, endpoint titers at Day 209 remained at least 4-fold higher than baseline.

- In the 18 to 55 years of age group, the S-2P ELISA GMT values on Day 209 were numerically higher in the 50 µg vaccination group compared with the other vaccination groups and were similar to the median GMT values for the convalescent sera control group. In both the 56 to 70 years and ≥71 years of age groups, the S-2P ELISA GMT values on Day 209 were numerically higher in the 100 µg vaccination groups compared with the other vaccination groups and were similar to the median GMT values for the convalescent sera control group.

S-2P RBD ELISA Endpoint

- After reaching a peak level between Day 36 and Day 43, the RBD ELISA GMT values decreased by Day 209; however, the values generally remained similar to or numerically higher than on Day 29 (except in the 50 µg and 250 µg vaccination groups in the 18 to 55 years of age group). Notably, endpoint titers at Day 209 remained at least 4-fold higher than baseline.

- In the 18 to 55 years of age group, the RBD ELISA GMT values on Day 209 were higher in the 100 µg vaccination group compared with the other vaccination groups. In both the 56 to 70 years and ≥71 years of age groups, the RBD ELISA GMT values on Day 209 were higher in the 50 g vaccination group compared with the other vaccination groups. Compared to the convalescent sera, the RBD ELISA GMT values on Day 209 were numerically higher in all participants except in the 25 µg (all age groups) and 50 µg (18 to 55 years of age group) vaccination groups.

Pseudovirus Neutralization ID_{50} and ID_{80}

- After reaching a peak level between Day 36 and Day 57, the PsVNA GM neutralizing ID_{50} and ID_{80} values decreased by Day 209; however, in general the values remained similar to or numerically higher than on Day 29. The values were lower than the median GM values for the convalescent sera control group.

- Across all age groups, the PsVNA GM neutralizing ID_{50} and ID_{80} values on Day 209 were higher in the 100 µg vaccination group compared with the 25 µg and 50 µg vaccination groups.

FRNT-mNG

- After reaching a peak level on Day 43, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values decreased by Day 209; however, the values remained similar to or numerically higher than on Day 29 (prior to the second injection) across all age groups and dose levels.

- Across all age groups, the FRNT-mNG GM neutralizing ID_{50} and ID_{80} values on Day 209 were higher in the 100 µg vaccination group compared with the 25 µg and

50 µg vaccination groups, and were similar to or numerically higher than values for convalescent sera controls.

Overall, mRNA-1273, administered as 2 doses 28 days apart, was safe 6 months after the second dose in healthy adult participants aged ≥ 18 years. The immune response elicited by mRNA-1273 persisted through 6 months after the second dose with the 100 µg dose regimen eliciting higher neutralizing antibody responses compared with the 25 or 50 µg dose across all age groups and higher binding antibody responses in the 56 to 70 years and ≥71 years of age groups.

10 References

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14 Tables and Figures

14.1 Demographic, Background, and Disposition Data

Demographic, background, and disposition data are provided in Day 119 CSR. Prior and concurrent medications summary tables are listed below.

Number	Title
Table 96	Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group All Subjects 18-55 Years of Age
Table 97	Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group All Subjects 56-70 Years of Age
Table 98	Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group All Subjects ≥71 years of Age

14.2 Immunogenicity Data

Number	Title
Table 1	Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group – S-2P – Age 18-55 Years, Per Protocol Population
Table 2	Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group – S-2P – Age 56-70 Years, Per Protocol Population
Table 3	Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group – S-2P – Age ≥71 Years, Per Protocol Population
Table 4	Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group – RBD – Age 18-55 Years, Per Protocol Population
Table 5	Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group – RBD – Age 56-70 Years, Per Protocol Population

14.3 Safety Data

14.3.1 Displays of Adverse Events

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

Number	Title
Table 79	Listing of New Serious Adverse Events
Table 80	Listing of New Adverse Events

14.3.3 Displays of Laboratory Values

Provided in the Day 119 CSR.

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

Data Listings (Each Subject) for Abnormal Clinically Meaningful Laboratory Values are provided in the Day 119 CSR (Appendix 16.2).

Individual participant data listings for vital signs, physical examinations, and concomitant medications are presented in Appendix 16.2.

14.4 Additional Safety Data

Number	Title
Table 81	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 18-55 Years of Age
Table 82	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 18-55 Years of Age
Table 83	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 18-55 Years of Age
Table 84	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 18-55 Years of Age
Table 85	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 18-55 Years of Age
Table 86	Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination Group – All Subjects 56-70 Years of Age

Table 96: 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	15	100	59	98
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	5	33	6	40	4	27	9	60	24	40
	Antibacterials For Systemic Use	1	7	3	20	1	7	1	7	6	10
	Antimycotics For Systemic Use	-	-	-	-	-	-	1	7	1	2
	Antivirals For Systemic Use	-	-	1	7	-	-	-	-	1	2
	Vaccines	4	27	5	33	3	20	9	60	21	35

		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**	**%**
Antineoplastic And Immunomodulating Agents	**Any Level 2 Codes**	-	-	-	-	-	-	-	-	-	-
	Antineoplastic Agents	-	-	-	-	-	-	-	-	-	-
	Endocrine Therapy	-	-	-	-	-	-	-	-	-	-
Blood And Blood Forming Organs	**Any Level 2 Codes**	2	13	-	-	2	13	3	20	7	12
	Antianemic Preparations	2	13	-	-	2	13	1	7	5	8
	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**	5	33	5	33	2	13	5	33	17	28
	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
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	1	7	-	-	1	7	2	3

		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**	**%**
	Antiseptics And Disinfectants	1	7	-	-	-	-	-	-	1	2
	Corticosteroids, Dermatological Preparations	2	13	1	7	-	-	1	7	4	7
	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	-	-	-	-	2	13	3	5
	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	8	53	11	73	9	60	39	65
	Antiinflammatory And Antirheumatic Products	11	73	8	53	11	73	9	60	39	65
	Drugs For Treatment Of Bone Diseases	-	-	-	-	-	-	-	-	-	-
	Muscle Relaxants	-	-	-	-	1	7	-	-	1	2
	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

		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**	**%**
	Analgesics	3	20	9	60	4	27	8	53	24	40
	Anesthetics	-	-	1	7	-	-	-	-	1	2
	Other Nervous System Drugs	-	-	-	-	1	7	-	-	1	2
	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	7	47	5	33	6	40	27	45
	Antihistamines For Systemic Use	6	40	6	40	4	27	4	27	20	33
	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	2	13	-	-	-	-	3	5
	Corticosteroids For Systemic Use	-	-	2	13	-	-	-	-	2	3
	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
	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 97: 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	6	60	5	50	18	60
	Antidiarrheals, Intestinal Antiinflammatory /Antiinfective Agents	-	-	2	20	-	-	2	7
	Antiemetics And Antinauseants	-	-	-	-	-	-	-	-
	Digestives, Incl. Enzymes	-	-	-	-	-	-	-	-
	Drugs For Acid Related Disorders	1	10	3	30	-	-	4	13
	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	6	60	5	50	17	57
Antiinfectives For Systemic Use	Any Level 2 Codes	8	80	8	80	7	70	23	77
	Antibacterials For Systemic Use	-	-	3	30	1	10	4	13
	Antimycotics For Systemic Use	1	10	-	-	-	-	1	3
	Antivirals For Systemic Use	2	20	-	-	2	20	4	13
	Vaccines	7	70	7	70	6	60	20	67

		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**	**%**
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
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	-	-	-	-	-	-

		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**	**%**
	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	8	80	7	70	21	70
	Antiinflammatory And Antirheumatic Products	6	60	7	70	7	70	20	67
	Drugs For Treatment Of Bone Diseases	3	30	2	20	1	10	6	20
	Muscle Relaxants	-	-	-	-	-	-	-	-
	Other Drugs For Disorders Of The Musculo-Skeletal System	-	-	-	-	-	-	-	-
Nervous System	**Any Level 2 Codes**	6	60	5	50	6	60	17	57

		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**	**%**
	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	3	30	6	20
	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
	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 98: 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	7	70	20	67
Antiinfectives For Systemic Use	Any Level 2 Codes	10	100	8	80	9	90	27	90
	Antibacterials For Systemic Use	-	-	1	10	1	10	2	7
	Antimycotics For Systemic Use	-	-	-	-	-	-	-	-
	Antivirals For Systemic Use	-	-	-	-	1	10	1	3
	Vaccines	10	100	8	80	8	80	26	87

		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**	**%**
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	4	40	8	27
	Antianemic Preparations	-	-	1	10	1	10	2	7
	Antithrombotic Agents	1	10	2	20	2	20	5	17
	Blood Substitutes And Perfusion Solutions	-	-	-	-	1	10	1	3
Cardiovascular System	**Any Level 2 Codes**	4	40	8	80	4	40	16	53
	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	3	30	12	40
	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
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	-	-	-	-	-	-	-	-

		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**	**%**
	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	4	40	-	-	7	23
	Gynecological Antiinfectives And Antiseptics	-	-	-	-	-	-	-	-
	Other Gynecologicals	-	-	-	-	-	-	-	-
	Sex Hormones And Modulators Of The Genital System	-	-	-	-	-	-	-	-
	Urologicals	3	30	4	40	-	-	7	23
Musculo-Skeletal System	**Any Level 2 Codes**	6	60	7	70	6	60	19	63
	Antiinflammatory And Antirheumatic Products	6	60	7	70	6	60	19	63
	Drugs For Treatment Of Bone Diseases	-	-	-	-	-	-	-	-
	Muscle Relaxants	-	-	-	-	1	10	1	3
	Other Drugs For Disorders Of The Musculo-Skeletal System	-	-	1	10	-	-	1	3
Nervous System	**Any Level 2 Codes**	9	90	7	70	5	50	21	70

		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**	**%**
	Analgesics	7	70	4	40	4	40	15	50
	Anesthetics	-	-	1	10	1	10	2	7
	Other Nervous System Drugs	-	-	-	-	1	10	1	3
	Psychoanaleptics	1	10	2	20	-	-	3	10
	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	1	10	-	-	-	-	1	3
	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
	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.

TABLE 1:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - 18-55 Years, 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	354	131	178	176	138901
	95% CI	72, 187	132, 946	65, 266	81, 392	122, 253	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	15	14	57	
	GMT	301540	180813	413971	604507	339860	
	95% CI	217148, 418729	109901, 297480	322891, 530744	451387, 809568	277755, 415852	
	n	13	15	15	14	57	

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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	GMT	81697	123538	84025	73802	89503	
	95% CI	51860, 128702	75890, 201101	60469, 116758	55937, 97372	74239, 107905	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.							

TABLE 2:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - 56-70 Years, 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	10	9	29	
	GMT	86391	75958	366252	129383	
	95% CI	51215, 145728	52421, 110063	213031, 629675	90051, 185894	
	n	10	9	9	28	

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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	GMT	28268	74682	119065	61326	
	95% CI	14754, 54161	55356, 100756	64592, 219478	42540, 88408	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 3:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - ≥71 Years, 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	10	30	
	GMT	75677	59815	195272	95971	
	95% CI	53020, 108016	32290, 110805	117647, 324112	69702, 132138	
	n	10	10	9	29	

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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	GMT	41508	62797	112298	65205	
	95% CI	31132, 55342	32886, 119915	57591, 218971	47444, 89613	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 4:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - 18-55 Years, 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	56	588	166	576	236	37244
	95% CI	44, 70	411, 840	82, 337	349, 949	169, 331	20170, 68771
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	15	14	57	
	GMT	140985	115090	235228	224653	171467	
	95% CI	79938, 248653	75489, 175465	177236, 312195	151320, 333524	139505, 210752	
	n	13	15	15	14	57	

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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	GMT	29001	24088	92451	57716	44372	
	95% CI	16804, 50052	14898, 38945	57148, 149562	39403, 84541	34230, 57519	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.							

TABLE 5:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - 56-70 Years, 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	10	9	29	
	GMT	45421	54066	151761	70136	
	95% CI	23045, 89526	36880, 79262	88571, 260033	49863, 98653	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GMT	20360	123781	62424	52136	

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
	95% CI	9275, 44693	69758, 219642	36765, 105990	33532, 81063	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 6:
Serum IgG ELISA Geometric Mean Titer (GMT) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - ≥71 Years, 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	10	30	
	GMT	65987	36403	157946	72394	
	95% CI	33240, 130995	15287, 86687	94345, 264420	47461, 110425	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GMT	22379	92133	49373	46603	

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
	95% CI	11232, 44591	35805, 237077	25171, 96849	29532, 73541	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 7:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - 18-55 Years, 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	15	14	57	
	GM	42487	38494	81372	88852	58876	
	95% CI	29443, 61310	25079, 59083	61678, 107354	66277, 119115	48855, 70953	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	13576	25387	23534	23991	21277	

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
	95% CI	8012, 23004	17108, 37672	17375, 31876	17368, 33139	17639, 25666	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.

TABLE 8:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - 56-70 Years, 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	10	9	29	
	GM	16624	19179	62227	26306	
	95% CI	9084, 30422	15235, 24144	39421, 98228	19081, 36266	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	4449	14747	18345	10311	

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
	95% CI	2125, 9314	9795, 22202	11234, 29956	7031, 15122	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.

TABLE 9:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - S2P - ≥71 Years, 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	10	30	
	GM	18687	14461	48171	23524	
	95% CI	12303, 28385	7645, 27354	29102, 79735	16903, 32738	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	5718	12847	18171	10822	

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
	95% CI	3518, 9294	7401, 22300	8555, 38594	7612, 15386	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 10:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - 18-55 Years, 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	0	9	2	14	3	4222
	95% CI	0, 0	5, 16	0, 4	6, 33	2, 6	2021, 8819
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	15	14	57	
	GM	25750	25417	45905	43401	33967	
	95% CI	14395, 46060	15307, 42204	32315, 65210	30790, 61179	27334, 42208	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	5497	7993	14794	11143	9363	

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
	95% CI	2933, 10298	4650, 13739	10367, 21111	7233, 17165	7342, 11940	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.

TABLE 11:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - 56-70 Years, 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	10	9	29	
	GM	9828	11721	36516	15695	
	95% CI	4667, 20697	8556, 16058	22002, 60604	11001, 22391	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	2216	9403	8750	5483	

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
	95% CI	946, 5186	5794, 15261	4865, 15736	3564, 8437	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 12:
Serum IgG ELISA Area Under the Curve (AUC) Results with 95% Confidence Intervals by Time Point and Treatment Group - RBD - ≥71 Years, 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	10	30	
	GM	11062	7660	29736	13608	
	95% CI	5901, 20739	2935, 19989	17627, 50162	8886, 20839	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	1803	6104	6418	4072	

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
	95% CI	853, 3813	2490, 14961	2843, 14486	2540, 6528	
Note: N=Number of Subjects. n=Number of subjects with results available at time point.						

TABLE 13:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - 18-55 Years, 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	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	15	14	57	
	GM	54	93	182	185	116	
	95% CI	29, 100	53, 162	112, 296	128, 269	89, 152	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	25	45	80	59	49	

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
	95% CI	15, 40	26, 79	48, 135	34, 103	37, 64	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 14:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - 56-70 Years, 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	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	10	9	29	
	GM	44	44	167	67	
	95% CI	20, 98	27, 73	88, 318	44, 100	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	18	18	57	26	

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
	95% CI	9, 35	11, 31	30, 106	18, 38	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 15:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - ≥71 Years, 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	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	10	30	
	GM	33	45	109	55	
	95% CI	19, 59	17, 117	68, 175	37, 82	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	12	27	59	26	

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
	95% CI	9, 17	12, 60	29, 121	17, 39	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 16:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - 18-55 Years, 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	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	15	14	57	
	GM	29	35	80	83	51	
	95% CI	17, 50	23, 54	52, 122	58, 119	40, 65	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	13	21	31	31	23	

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
	95% CI	10, 17	15, 31	22, 44	21, 46	19, 28	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 17:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - 56-70 Years, 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	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	
	GM	10	10	10	10	
	95% CI	NE	NE	NE	NE	
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	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	
	GM	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	
	GM	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	
	GM	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	10	9	29	
	GM	24	16	70	29	
	95% CI	12, 46	11, 25	45, 109	21, 42	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	12	11	27	15	

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
	95% CI	8, 17	9, 15	15, 51	12, 20	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 18:
Pseudovirus Neutralization Assay Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - ≥71 Years, 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	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	
	GM	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	10	30	
	GM	15	22	52	26	
	95% CI	10, 23	11, 46	32, 87	19, 37	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	10	17	25	16	

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
	95% CI	NE	10, 29	14, 45	12, 21	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 19:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - 18-55 Years, 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=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GM	10	10	10	10	10	129
	95% CI	NE	NE	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GM	23	41	69	77	47	
	95% CI	13, 39	24, 72	46, 102	43, 136	36, 61	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GM	622	1207	1388	1575	1144	
	95% CI	374, 1034	799, 1821	1056, 1825	1206, 2058	943, 1388	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	309	382	775	599	489	
	95% CI	184, 517	241, 605	560, 1071	437, 821	397, 603	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	147	65	361	403	192	
	95% CI	93, 234	39, 106	258, 504	282, 575	146, 253	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 20:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - 56-70 Years, 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=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	10	10	10	10	129
	95% CI	NE	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	19	15	80	28	
	95% CI	11, 32	10, 23	52, 123	20, 41	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GM	550	735	1425	817	
	95% CI	302, 1001	533, 1013	980, 2072	621, 1074	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	9	29	
	GM	227	210	685	311	
	95% CI	131, 392	156, 284	436, 1077	230, 422	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	51	64	171	81	
	95% CI	25, 107	41, 100	95, 307	56, 117	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 21:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{50} - ≥71 Years, 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=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	10	10	10	10	129
	95% CI	NE	NE	NE	NE	78, 214
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	18	16	39	22	
	95% CI	12, 29	9, 28	18, 86	16, 32	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GM	448	461	900	571	
	95% CI	299, 672	182, 1169	575, 1409	404, 806	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	10	30	
	GM	183	146	552	245	
	95% CI	123, 272	55, 385	321, 947	163, 369	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	35	45	131	57	
	95% CI	21, 57	19, 106	69, 251	38, 86	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 22:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - 18-55 Years, 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=45)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	15	15	15	15	60	41
	GM	10	10	10	10	10	37
	95% CI	NE	10, 10	NE	NE	10, 10	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	15	15	15	14	59	
	GM	12	15	25	20	17	
	95% CI	10, 15	10, 21	18, 33	13, 32	15, 20	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	13	14	14	14	55	
	GM	234	356	525	487	385	
	95% CI	144, 381	230, 549	416, 663	382, 619	321, 463	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	89	122	237	196	152	
	95% CI	49, 160	72, 208	170, 332	143, 270	121, 191	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57	
	GM	45	30	126	118	67	
	95% CI	25, 79	18, 51	88, 180	80, 174	52, 88	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 23:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - 56-70 Years, 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=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	10	10	10	10	37
	95% CI	NE	NE	NE	NE	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	10	10	17	12	
	95% CI	NE	NE	11, 25	10, 14	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	9	29	
	GM	167	221	583	271	
	95% CI	101, 277	162, 300	400, 851	203, 362	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	9	29	
	GM	71	58	233	95	
	95% CI	34, 148	38, 88	145, 375	66, 138	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28	
	GM	19	24	59	30	
	95% CI	12, 33	12, 46	32, 108	21, 42	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 24:
FRNT mNG Geometric Mean (GM) Results with 95% Confidence Intervals by Time Point and Treatment Group - ID_{80} - ≥71 Years, 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=20)	Convalescent Sera
Day 1 (Pre-Vaccination 1)	n	10	10	10	30	41
	GM	10	10	10	10	37
	95% CI	NE	NE	NE	NE	24, 57
Day 29 Post Vaccination 1 (Pre-Vaccination 2)	n	10	10	10	30	
	GM	11	11	15	12	
	95% CI	9, 14	9, 13	9, 25	10, 15	
Day 43 Post Vaccination 1 (14 Days Post Vaccination 2)	n	10	10	10	30	
	GM	169	138	392	209	
	95% CI	107, 268	51, 378	252, 609	142, 308	
Day 119 Post Vaccination 1 (90 Days Post Vaccination 2)	n	10	10	10	30	
	GM	52	45	190	76	
	95% CI	30, 90	18, 115	115, 317	50, 117	
Day 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29	
	GM	14	24	44	24	
	95% CI	9, 23	12, 49	20, 99	17, 35	

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable

TABLE 25:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - 18-55 Years, 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	190.6	656.6	915.8	422.8
	95% CI	120.712, 644.309	92.847, 391.123	327.061, 1318.056	418.821, 2002.329	288.26, 620.126
	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	334.4	831	1259.5	583.1
	95% CI	170.898, 707.61	129.84, 861.462	379.435, 1819.776	533.04, 2975.799	389.195, 873.694
	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	2450.1	5945.5	7443.6	4247.5
	95% CI	1440.586, 6127.2	828.366, 7246.885	2824.739, 12514.226	3258.379, 17004.433	2812.81, 6413.817
	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	2512.7	6381.4	5866.7	4084.2
	95% CI	1489.891, 5588.303	1008.588, 6259.775	2845.746, 14310.027	2489.211, 13826.839	2774.653, 6011.91
	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	1589.1	6158	7404.7	3561.2

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)
	95% CI	1061.856, 4884.982	666.396, 3789.303	3200.137, 11849.779	2850.706, 19233.461	2359.649, 5374.61
	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	15	14	57
	GMFR[a]	2291.1	511.2	3149.8	3565.6	1871.4
	95% CI	1210.086, 4337.908	162.727, 1605.905	1628.983, 6090.592	1347.745, 9433.154	1185.722, 2953.625
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	620.7	349.3	639.3	435.3	492.8
	95% CI	277.503, 1388.53	133.34, 914.873	330.825, 1235.535	176.912, 1071.116	334.884, 725.304
	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%

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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 26:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - 56-70 Years, 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

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)
	95% CI	428.352, 6880.259	319.822, 978.087	306.421, 11310.5	599.411, 2385.743
	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	10	9	29
	GMFR[a]	457.8	134.9	576.3	322.6
	95% CI	131.067, 1599.219	68.79, 264.363	173.445, 1915.046	179.219, 580.728
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28
	GMFR[a]	149.8	127.5	187.4	152.9
	95% CI	41.612, 539.297	64.77, 251.145	47.864, 733.404	85.359, 273.737
	4-Fold Rise[b]	10/10 (100%)	9/9 (100%)	9/9 (100%)	28/28 (100%)
	95% CI	69.2%, 100%	66.4%, 100%	66.4%, 100%	87.7%, 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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 27:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - ≥71 Years, 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

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)
	95% CI	3722.344, 27793.388	164.278, 1424.865	1263.313, 11527.479	1292.484, 5466.303
	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	10	30
	GMFR[a]	682.2	184.3	204.8	295.3
	95% CI	271.77, 1712.245	51.008, 665.97	103.019, 407.152	170.46, 511.549
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	374.2	193.5	114.7	206.5
	95% CI	148.346, 943.69	64.24, 582.833	42.79, 307.271	120.419, 354.086
	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%

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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 28:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - 18-55 Years, 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

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)
	95% CI	1989.818, 5320.999	557.835, 1379.568	963.92, 5697.1	494.474, 2202.725	1135.132, 2221.189
	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	15	14	57
	GMFR[a]	2497.9	195.8	1416.7	415.5	708.6
	95% CI	1363.387, 4576.607	117.337, 326.631	685.114, 2929.333	209.466, 824.301	478.203, 1050.109
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	513.8	41	556.8	106.8	183.4
	95% CI	295.988, 892.018	23.078, 72.746	290.508, 1067.127	53.736, 212.083	121.865, 275.944
	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%

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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 29:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - 56-70 Years, 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

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)
	95% CI	156.909, 936.467	249.122, 1341.482	379.042, 9752.418	390.374, 1359.569
	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	10	9	29
	GMFR[a]	223.1	154.9	576.2	264.1
	95% CI	82.895, 600.403	61.401, 390.687	168.76, 1967.559	150.403, 463.67
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28
	GMFR[a]	100	285.7	237	184.9
	95% CI	33.504, 298.483	140.889, 579.476	74.579, 753.296	108.009, 316.665
	4-Fold Rise[b]	10/10 (100%)	9/9 (100%)	9/9 (100%)	28/28 (100%)
	95% CI	69.2%, 100%	66.4%, 100%	66.4%, 100%	87.7%, 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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 30:
Serum IgG ELISA Geometric Mean Titer (GMT) Geometric Mean Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - ≥71 Years, 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

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)
	95% CI	480.831, 8012.1	180.418, 2174.381	270.671, 3001.108	527.738, 2028.964
	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	10	30
	GMFR[a]	593.4	187.8	313.9	327.1
	95% CI	150.964, 2332.394	59.46, 593.339	88.358, 1115.129	168.719, 634.005
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	201.2	475.4	91.9	212.3
	95% CI	52.196, 775.907	153.082, 1476.266	27.678, 305.432	108.581, 414.951
	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%

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 endpoint titer compared to pre-dose 1
[b]4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in endpoint titer compared to pre-dose 1

TABLE 31:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - 18-55 Years, 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	2940	28300.6	39579.8	14525.3
	95% CI	4705.476, 38830.697	797.952, 10831.866	8319.721, 96267.799	11551.751, 135612.504	7912.528, 26664.526
	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	4138.7	30463	53290.8	18765.4
	95% CI	7164.525, 54643.201	978.947, 17497.313	9185.964, 101023.082	14486.651, 196036.104	10108.5, 34836.088
	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	37233.4	316250.4	437609.9	175214.7
	95% CI	76518.696, 510028.44	7985.397, 173607.57	95307.907, 1049380.846	116316.547, 1646389.964	92459.122, 332040.847
	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	50942.4	348444.2	352576.7	185487
	95% CI	73319.816, 489394.379	12584.09, 206222.758	104253.422, 1164598.06	89054.744, 1395886.778	101206.587, 339952.6
	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	27667.6	231292.3	301901.8	128880
	95% CI	65611.312, 400099.793	6580.565, 116326.529	71428.076, 748950.815	72359.981, 1259601.233	68558.305, 242276.478

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	15	14	57
	GMFR[a]	88363.1	10104.7	120772.9	123153.4	58825.4
	95% CI	37510.935, 208153.648	2150.804, 47473.295	38894.992, 375012.131	30463.478, 497866.665	30824.751, 112261.252
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	28233.5	6664.1	34928.6	33252.7	21258.5
	95% CI	10435.927, 76383.099	1461.695, 30382.819	11153.338, 109384.933	8474.079, 130485.177	11529.962, 39195.62
	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%

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 32:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - 56-70 Years, 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	10	9	29
	GMFR[a]	15538.9	1790.4	11733.9	6760.1
	95% CI	3376.496, 71511.032	611.797, 5239.35	1533.426, 89789.288	2847.611, 16048.103
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28
	GMFR[a]	4157.6	1288.8	3459.2	2689.5
	95% CI	926.105, 18664.773	387.716, 4283.921	455.447, 26272.698	1178.738, 6136.526
	4-Fold Rise[b]	10/10 (100%)	9/9 (100%)	9/9 (100%)	28/28 (100%)
	95% CI	69.2%, 100%	66.4%, 100%	66.4%, 100%	87.7%, 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 33:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - S2P - ≥71 Years, 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	10	30
	GMFR[a]	30055.9	4328.9	3275.3	7525.2
	95% CI	6099.06, 148113.781	667.001, 28094.672	1284.014, 8354.491	3211.268, 17634.223
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	9196.9	3845.8	1109	3531.4
	95% CI	1831.983, 46170.183	657.395, 22497.929	358.418, 3431.316	1512.022, 8247.918
	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%

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 34:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - 18-55 Years, 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	15	14	57
	GMFR[a]	142175.1	2966	52458	3784.5	16210.6
	95% CI	79548.615, 254105.676	1407.299, 6251.158	17308.628, 158986.983	1219.519, 11744.035	8794.492, 29880.423
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	13	15	15	14	57
	GMFR[a]	30345.6	932.7	16905.7	971.6	4468.3
	95% CI	16372.922, 56242.507	440.066, 1976.619	5483.123, 52123.89	302.945, 3115.868	2435.885, 8196.503
	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%

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 35:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - 56-70 Years, 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	10	9	29
	GMFR[a]	6643.5	2063.3	21716.1	6410.9
	95% CI	1526.9, 28905.311	419.399, 10150.617	4197.282, 112355.335	2693.578, 15258.185
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	9	9	28
	GMFR[a]	1497.2	1123.2	5203.2	2037.3
	95% CI	333.638, 6718.444	275.151, 4585.399	981.33, 27588.472	911.504, 4553.485
	4-Fold Rise[b]	10/10 (100%)	9/9 (100%)	9/9 (100%)	28/28 (100%)
	95% CI	69.2%, 100%	66.4%, 100%	66.4%, 100%	87.7%, 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 36:
Serum IgG ELISA Area Under the Curve (AUC) Geometric Fold Rise (GMFR) and 4-Fold Rise Results by Time Point and Treatment Group
Treatment Group - RBD - ≥71 Years, 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	10	30
	GMFR[a]	21900.8	4029	6808.6	8438
	95% CI	3161.376, 151719.789	724.355, 22410.578	1190.524, 38938.675	3276.034, 21733.639
	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 209 Post Vaccination 1 (180 Days Post Vaccination 2)	n	10	10	9	29
	GMFR[a]	3569.2	3210.6	1303	2517.1
	95% CI	467.988, 27220.813	614.058, 16786.949	216.048, 7858.47	985.539, 6428.722
	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%

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 1: Reverse Cumulative Distribution of Serum IgG Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

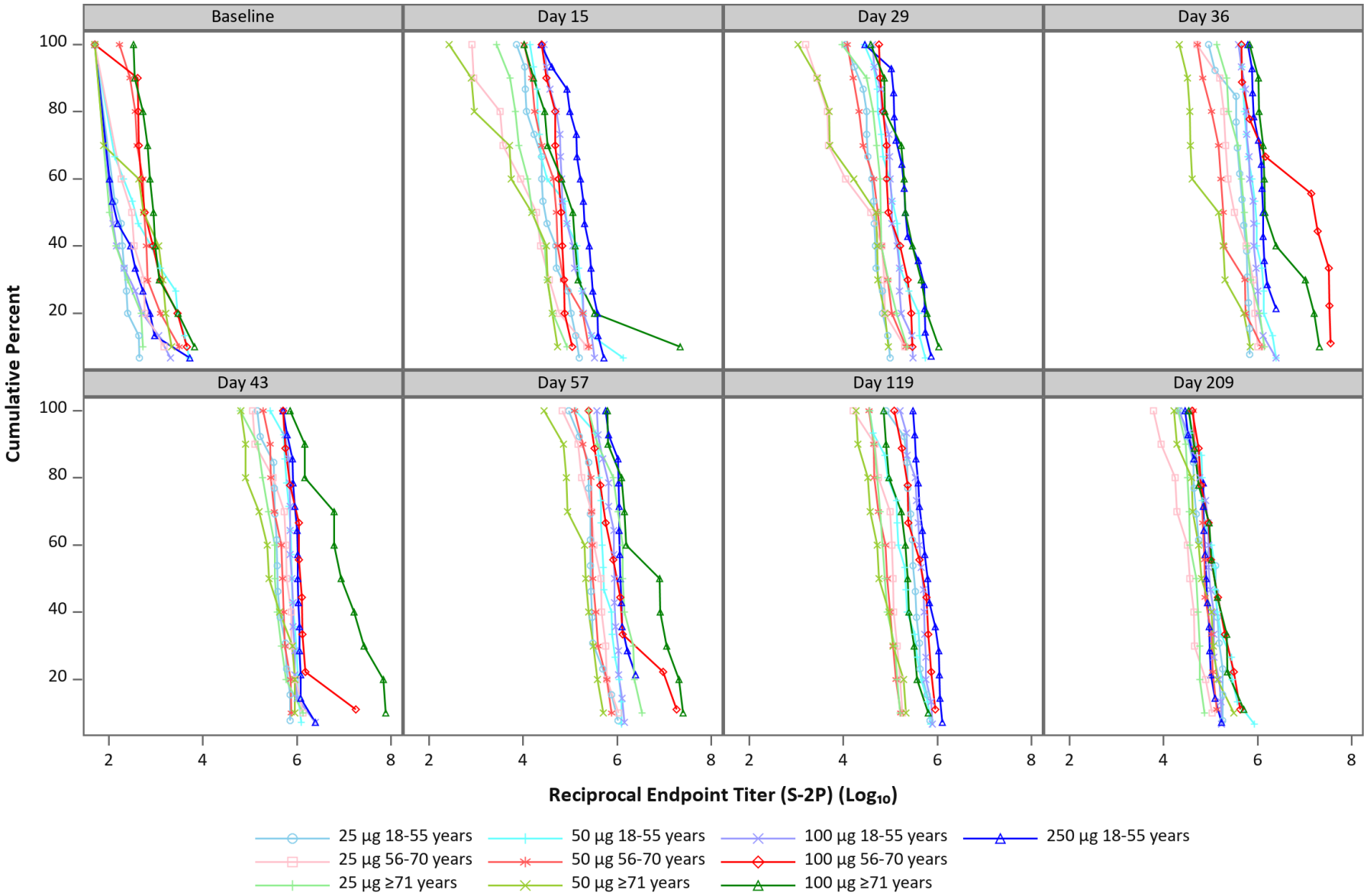

Figure 2: Reverse Cumulative Distribution of Serum IgG Endpoint Titer Values by Time Point and Treatment Group - RBD, Per Protocol Population

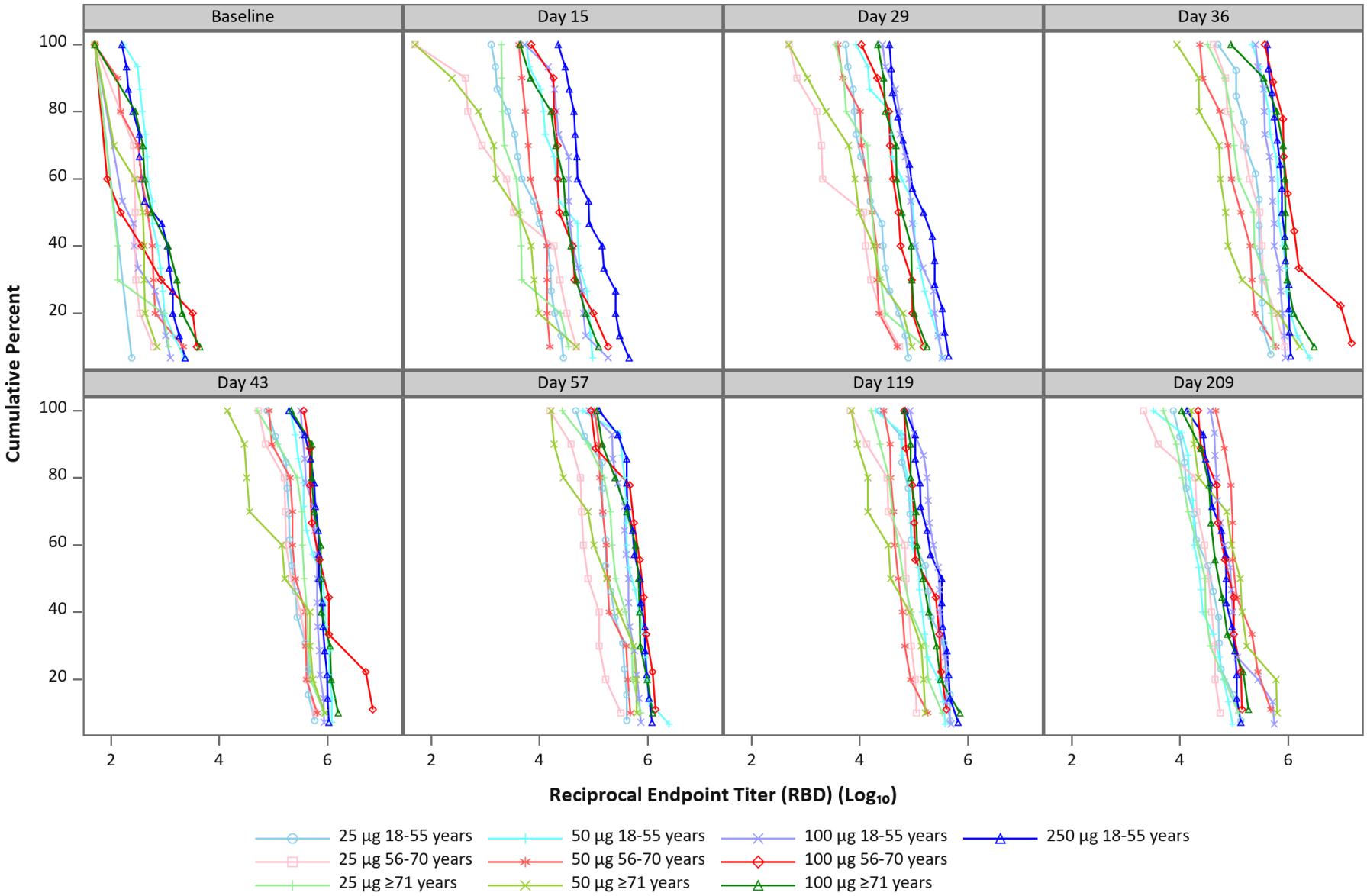

Figure 3: Reverse Cumulative Distribution of Serum IgG Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

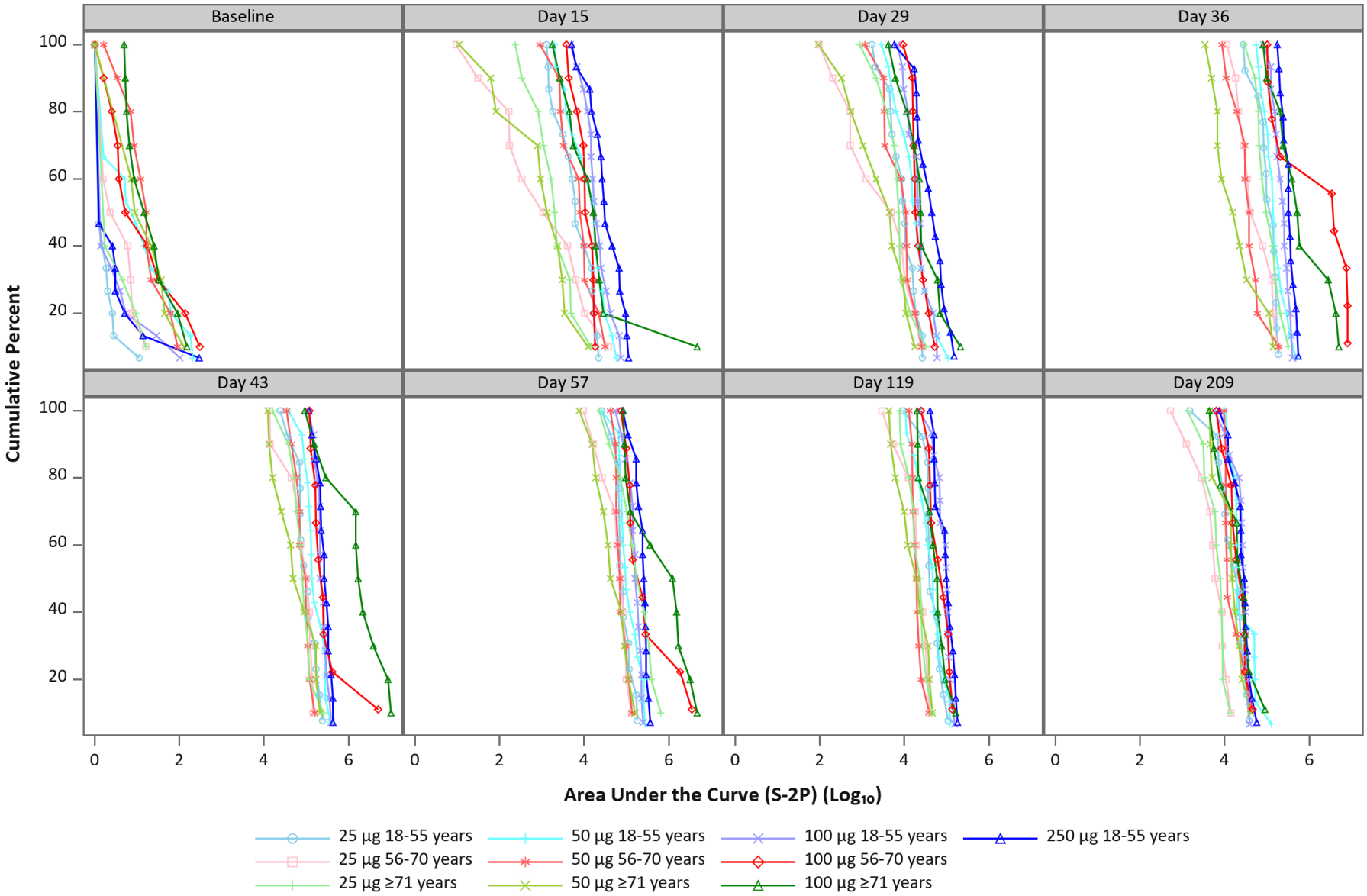

Figure 4: Reverse Cumulative Distribution of Serum IgG Area Under the Curve (AUC) Values by Time Point and Treatment Group - RBD, Per Protocol Population

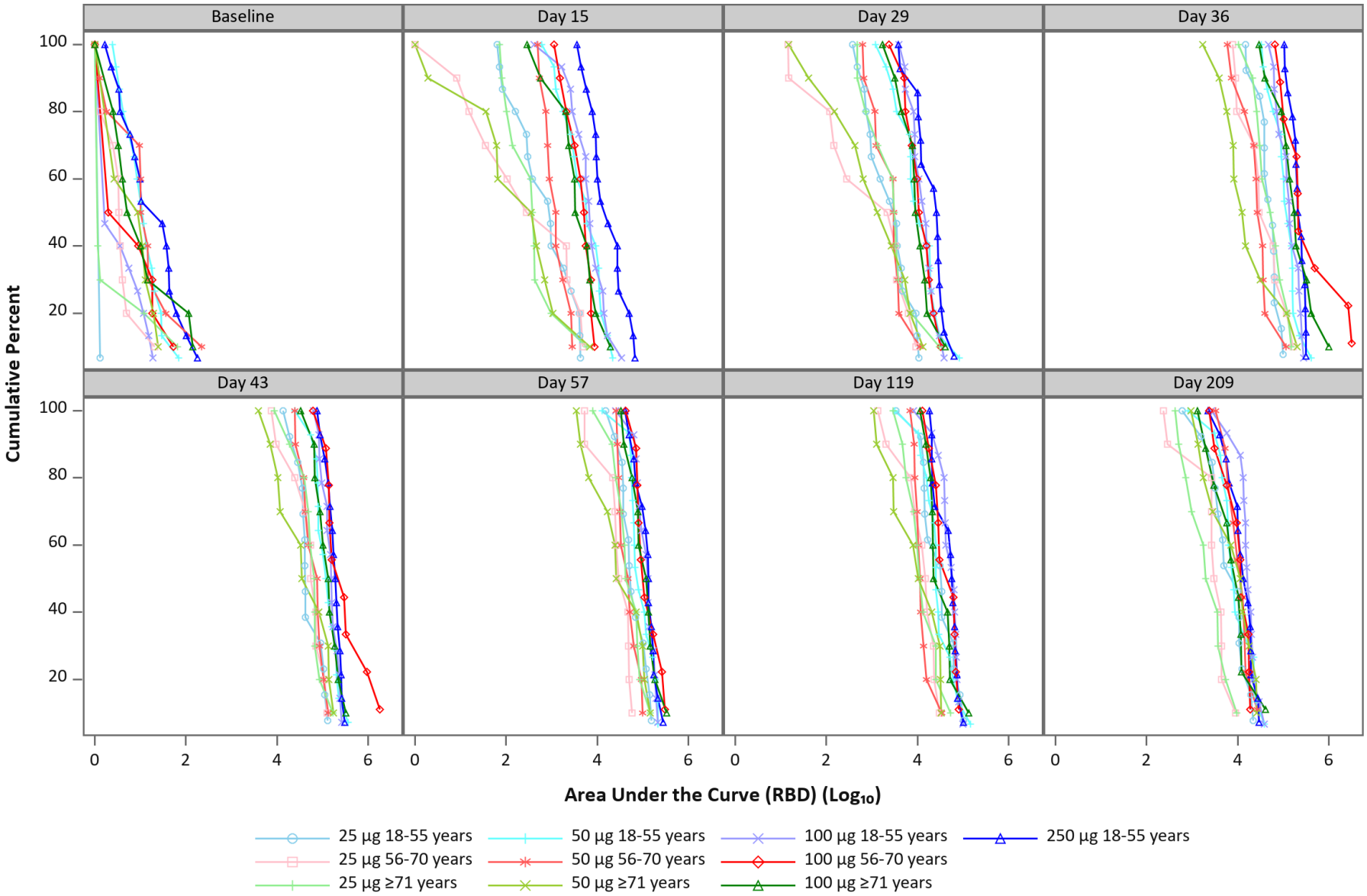

Figure 5: Serum IgG ELISA Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

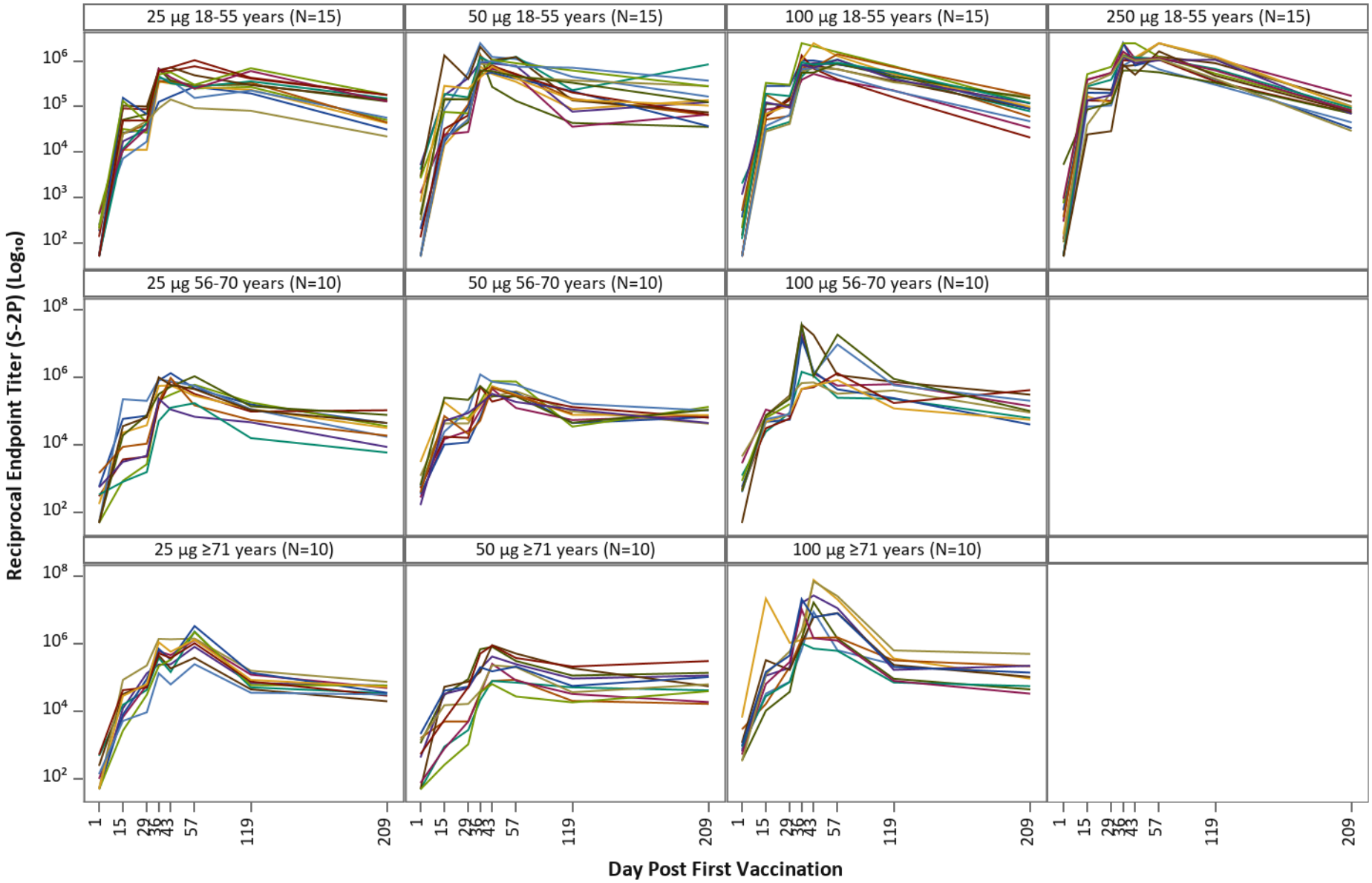

Figure 6: Serum IgG ELISA Endpoint Titer Values by Time Point and Treatment Group – RBD, Per Protocol Population

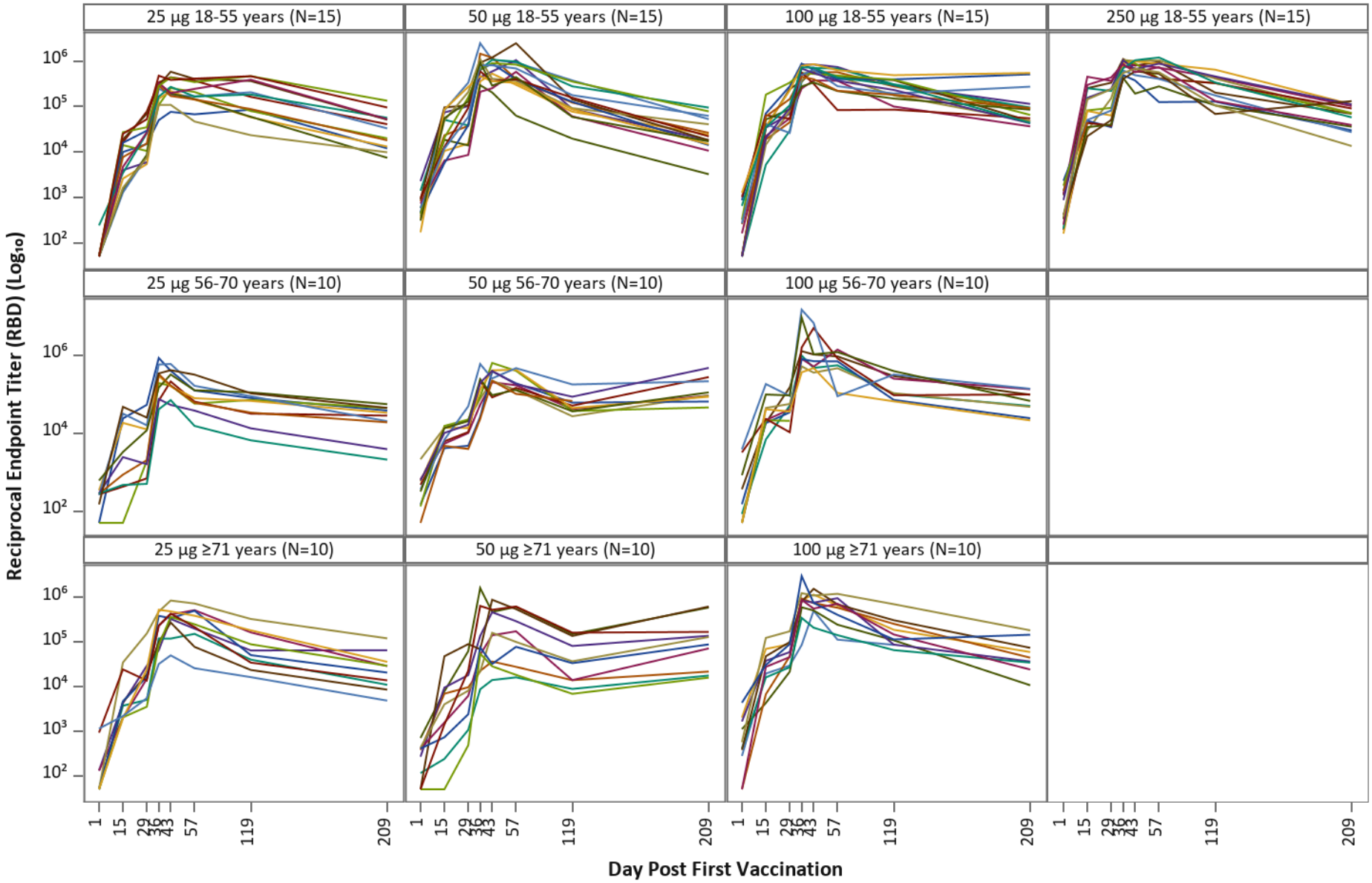

Figure 7: Serum IgG ELISA Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

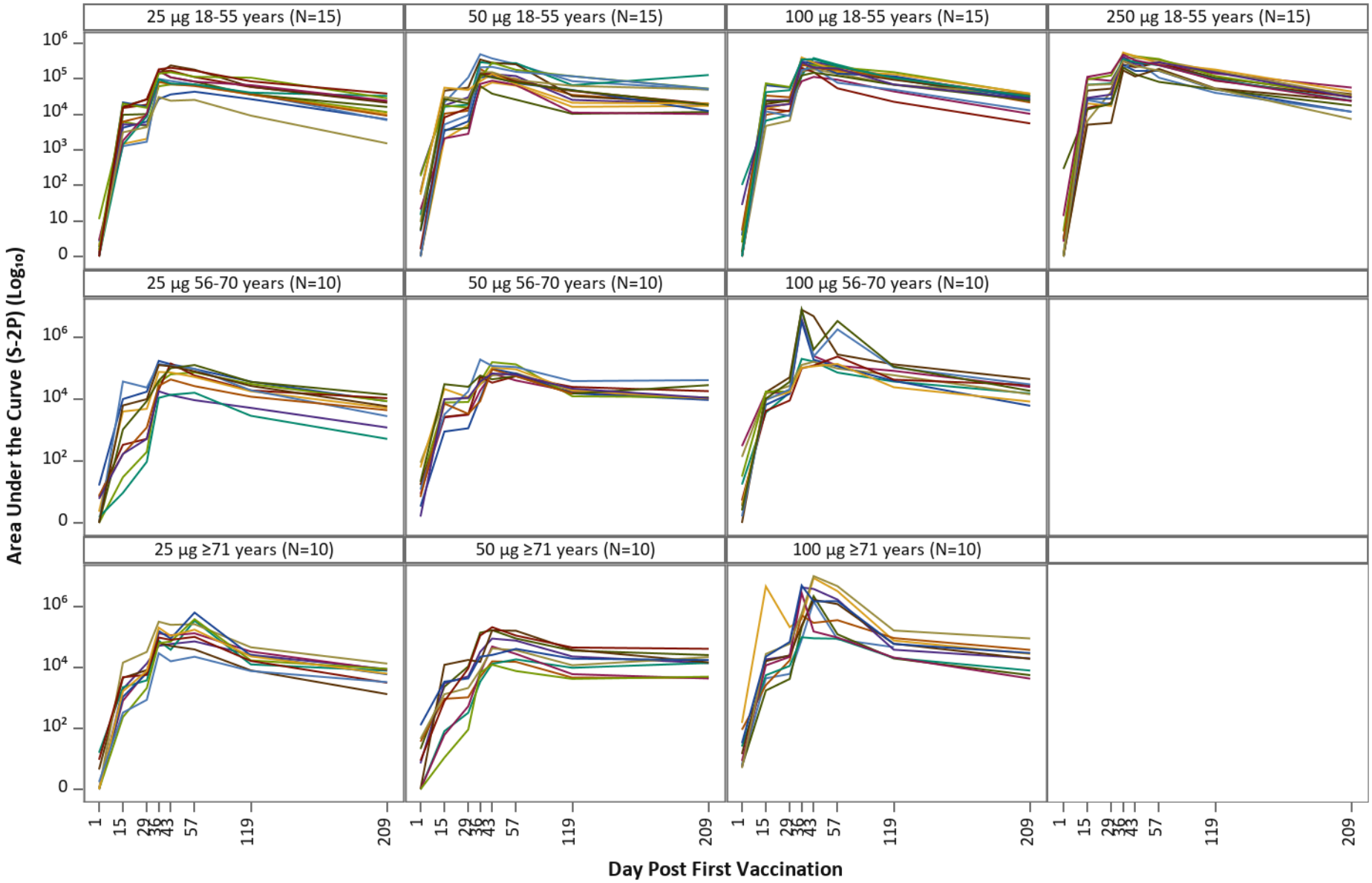

Figure 8: Serum IgG ELISA Area Under the Curve (AUC) Values by Time Point and Treatment Group – RBD, Per Protocol Population

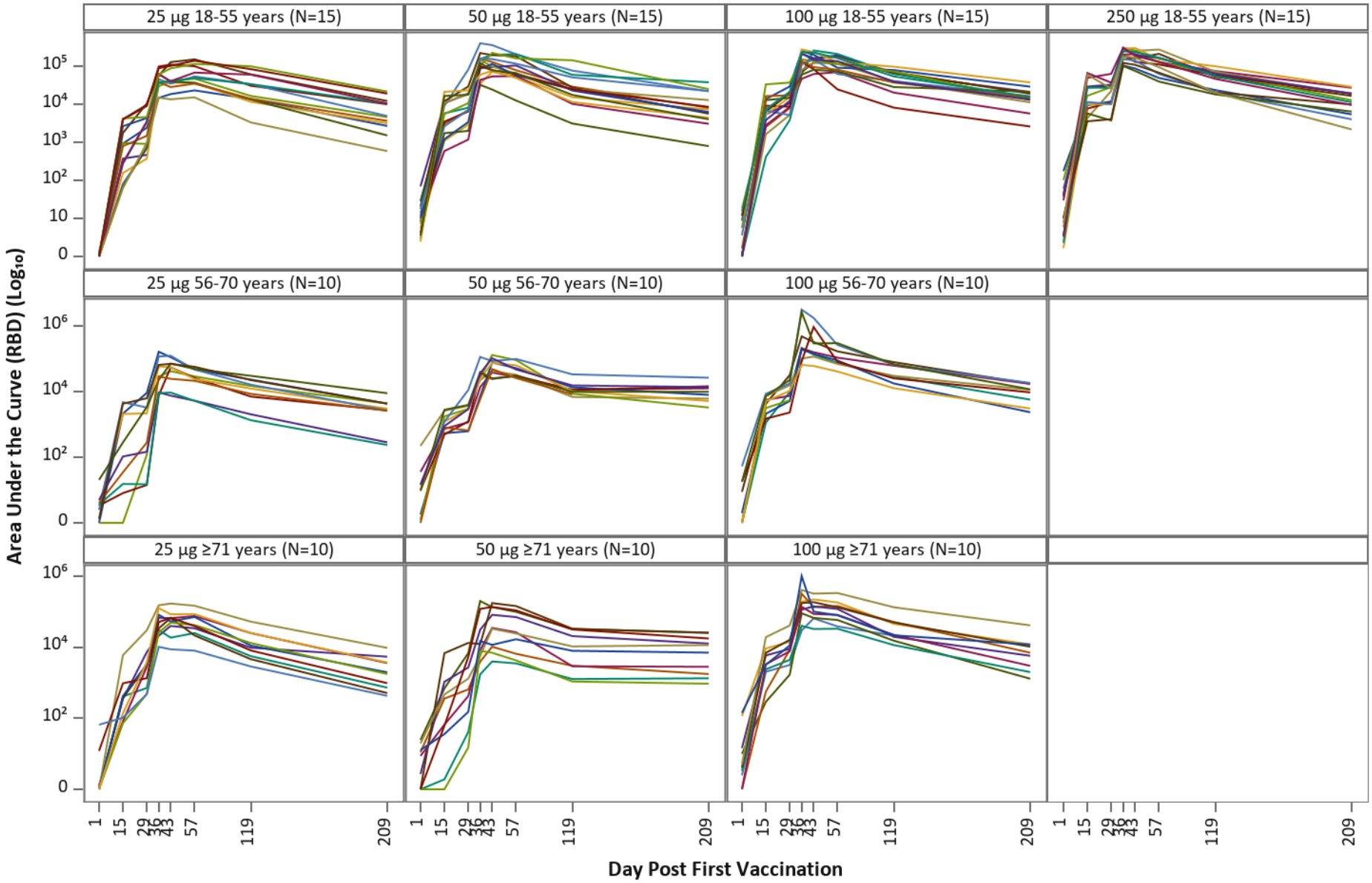

Figure 9: Pseudovirus Neutralization Assay Titers by Time Point and Treatment Group - ID50, Per Protocol Population

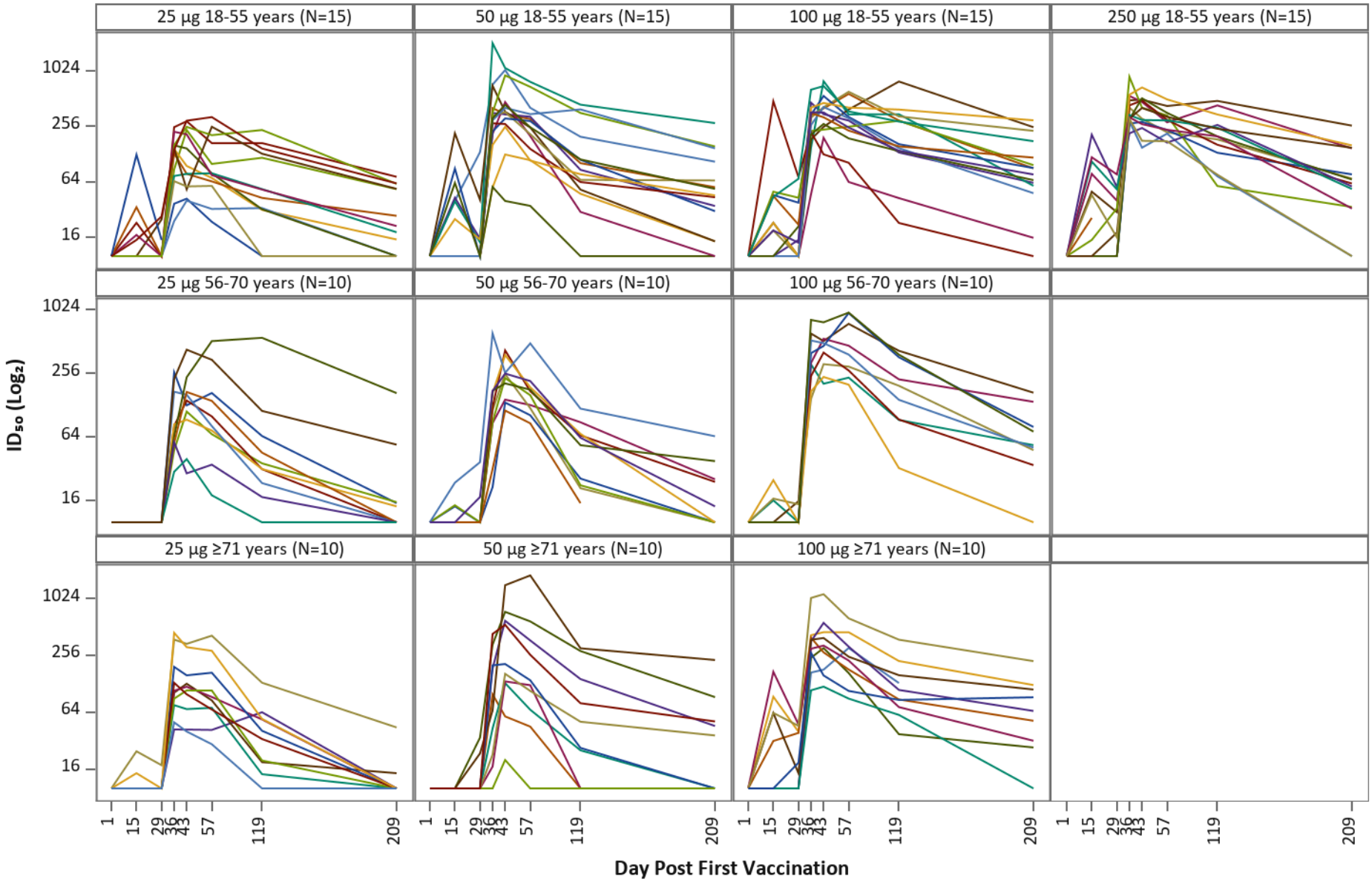

Figure 10: Pseudovirus Neutralization Assay Titers by Time Point and Treatment Group – ID80, Per Protocol Population

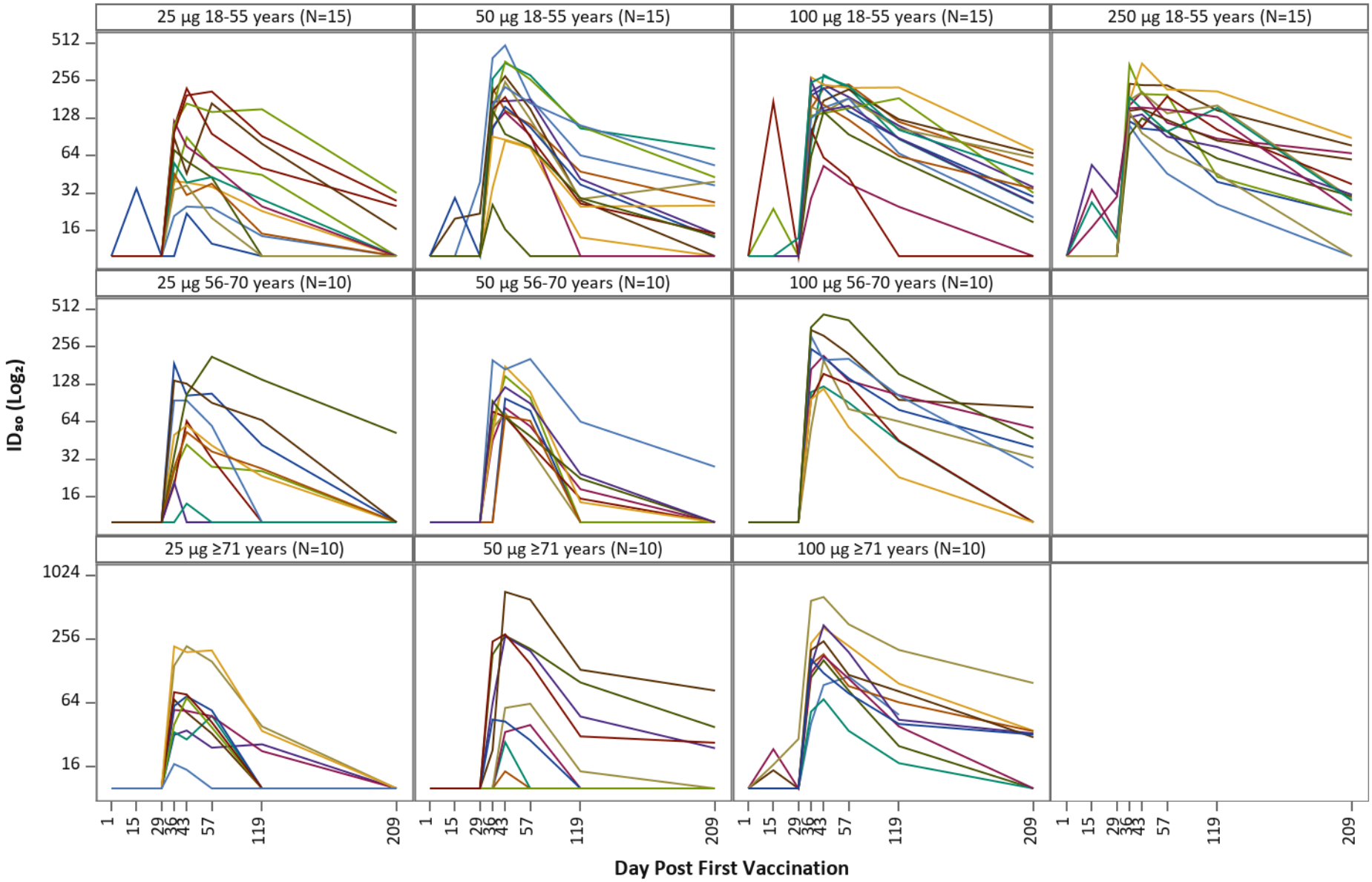

Figure 11: Geometric Mean Endpoint Titer Values by Time Point and Treatment Group - S-2P, Per Protocol Population

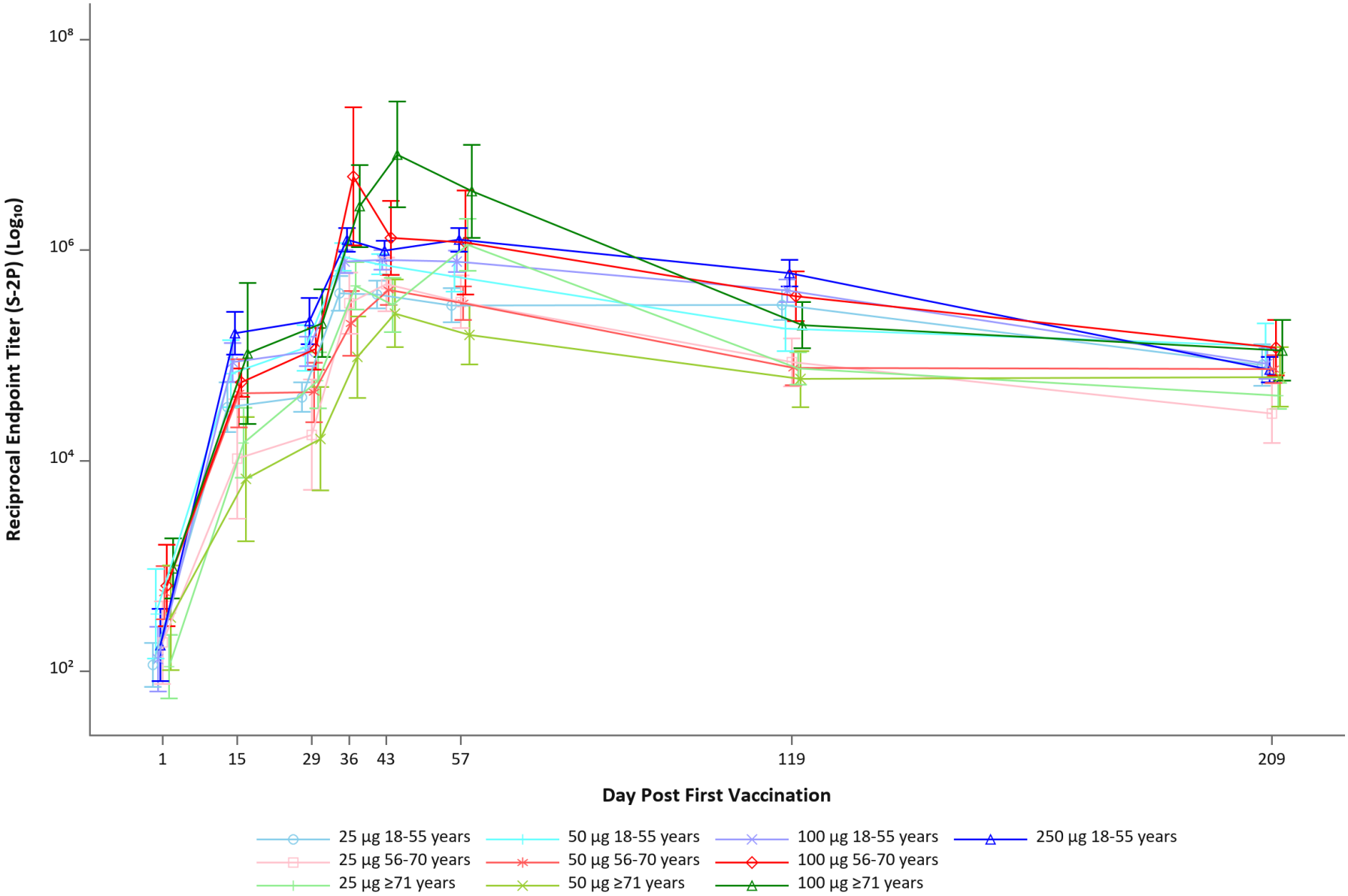

Figure 12: Geometric Mean Endpoint Titer Values by Time Point and Treatment Group - RBD, Per Protocol Population

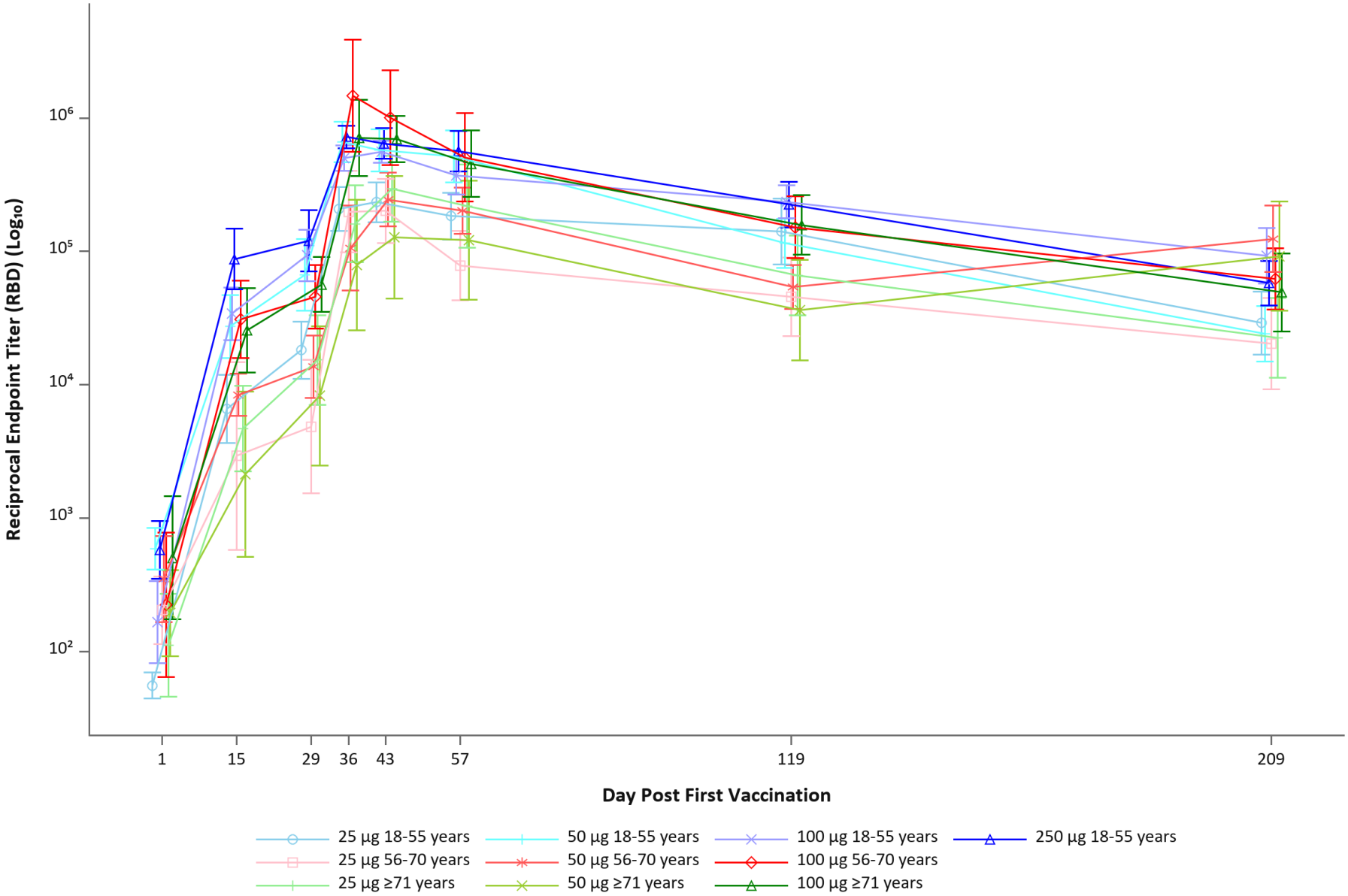

Figure 13: Geometric Mean Area Under the Curve (AUC) Values by Time Point and Treatment Group - S-2P, Per Protocol Population

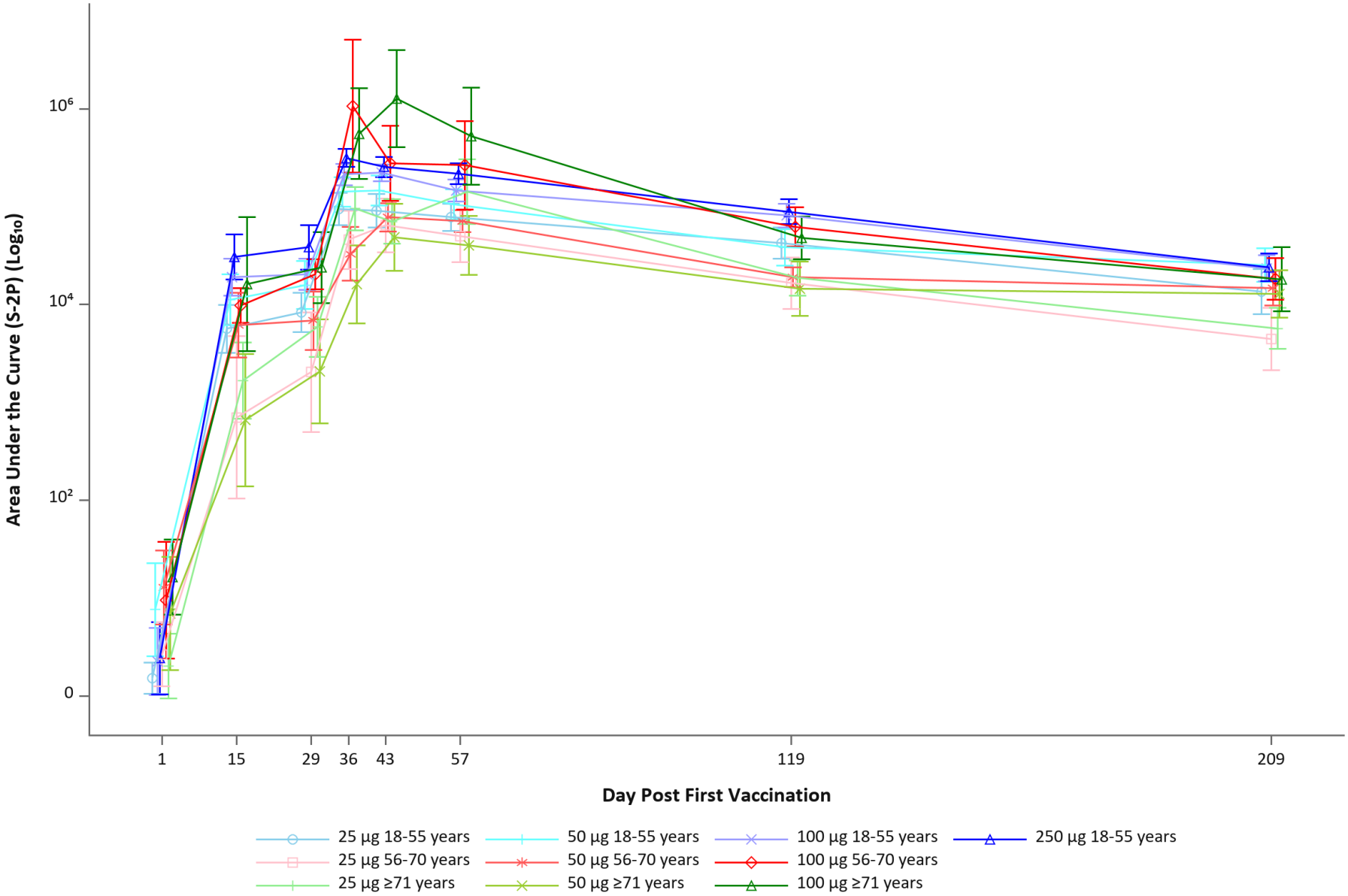

Figure 14: Geometric Mean Area Under the Curve (AUC) Values by Time Point and Treatment Group - RBD, Per Protocol Population

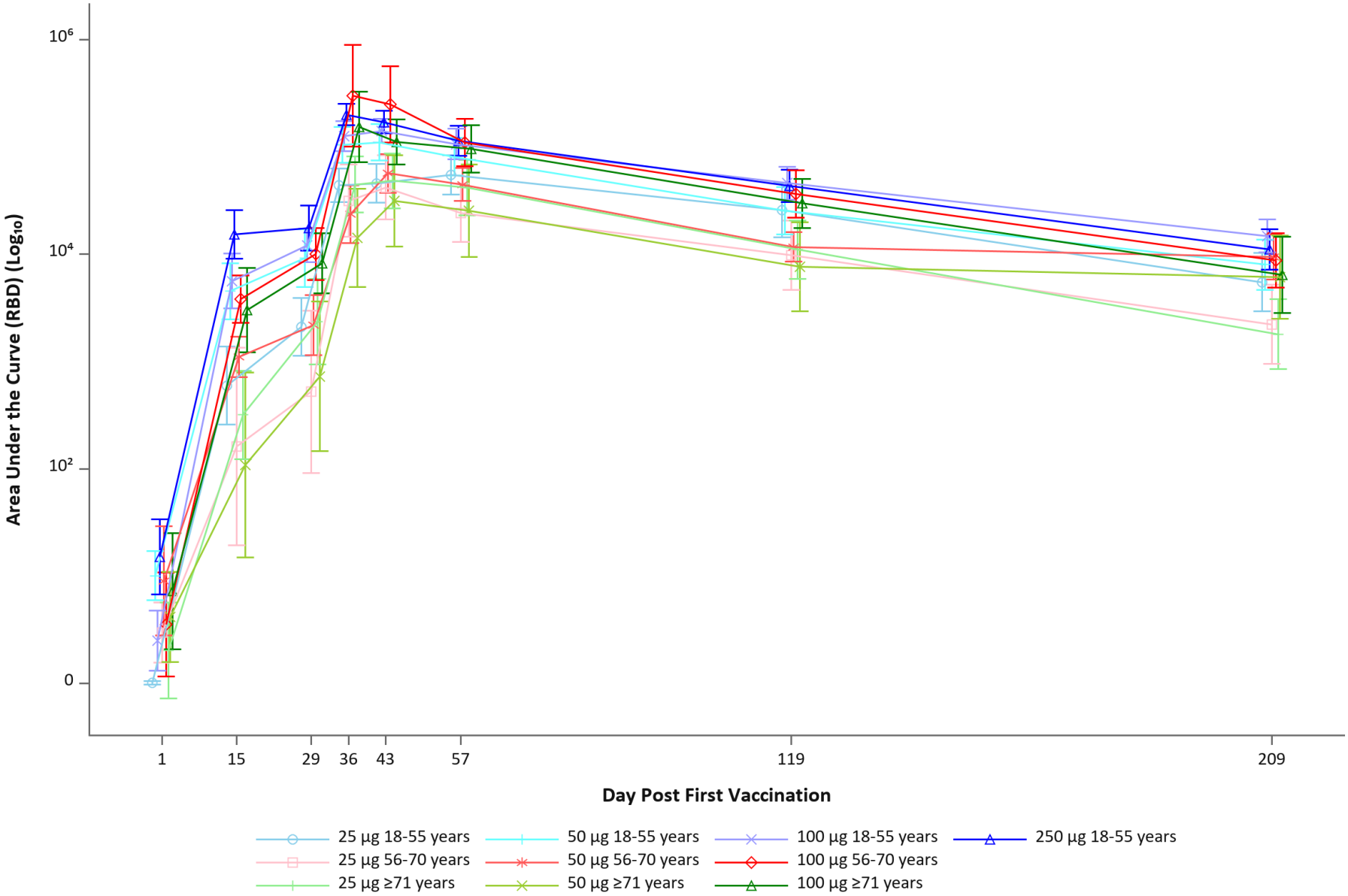

Figure 15: Pseudovirus Neutralization Assay GM by Time Point and Treatment Group - ID_{50}, Per Protocol Population

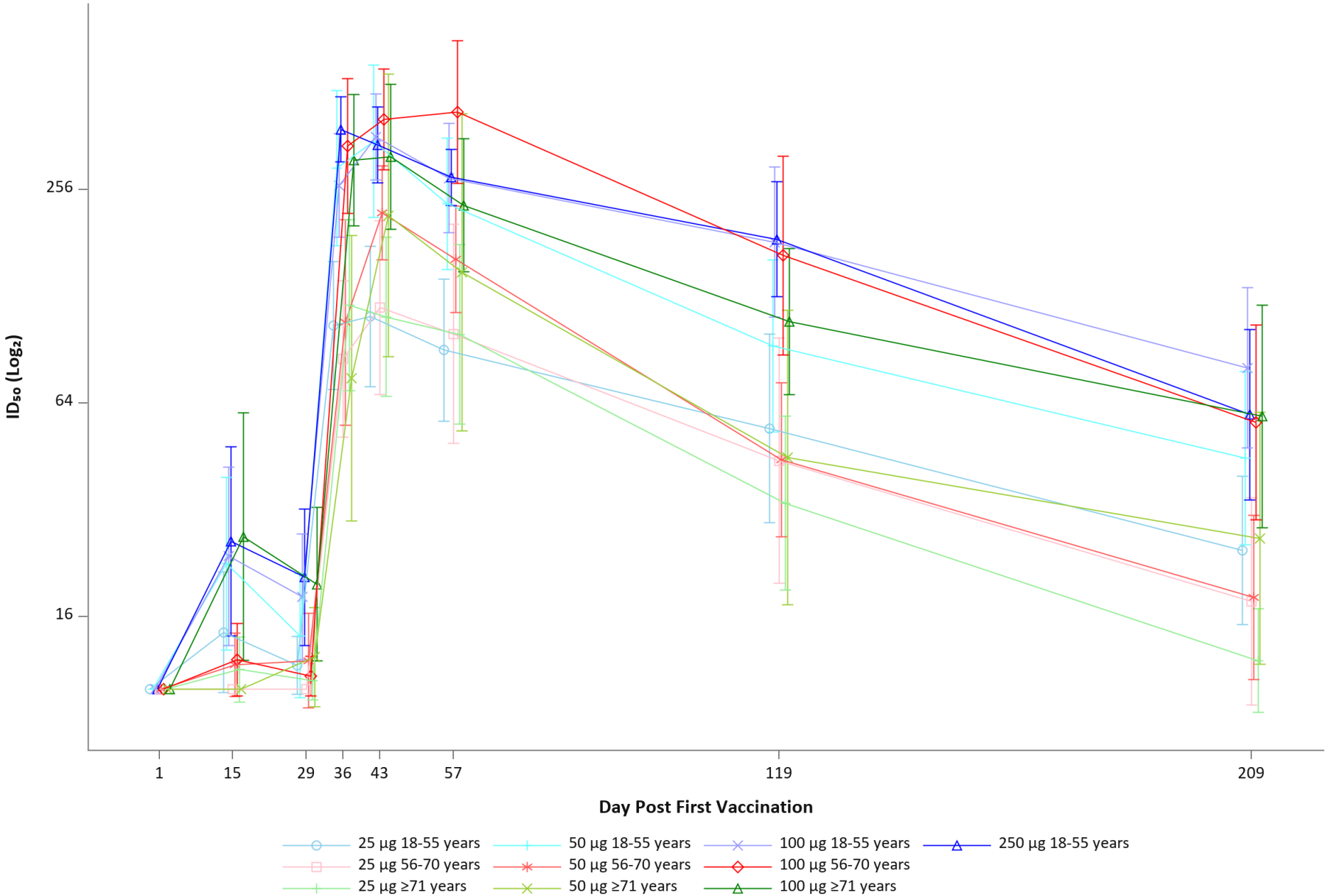

Figure 16: Pseudovirus Neutralization Assay GM by Time Point and Treatment Group - ID_{80}, Per Protocol Population

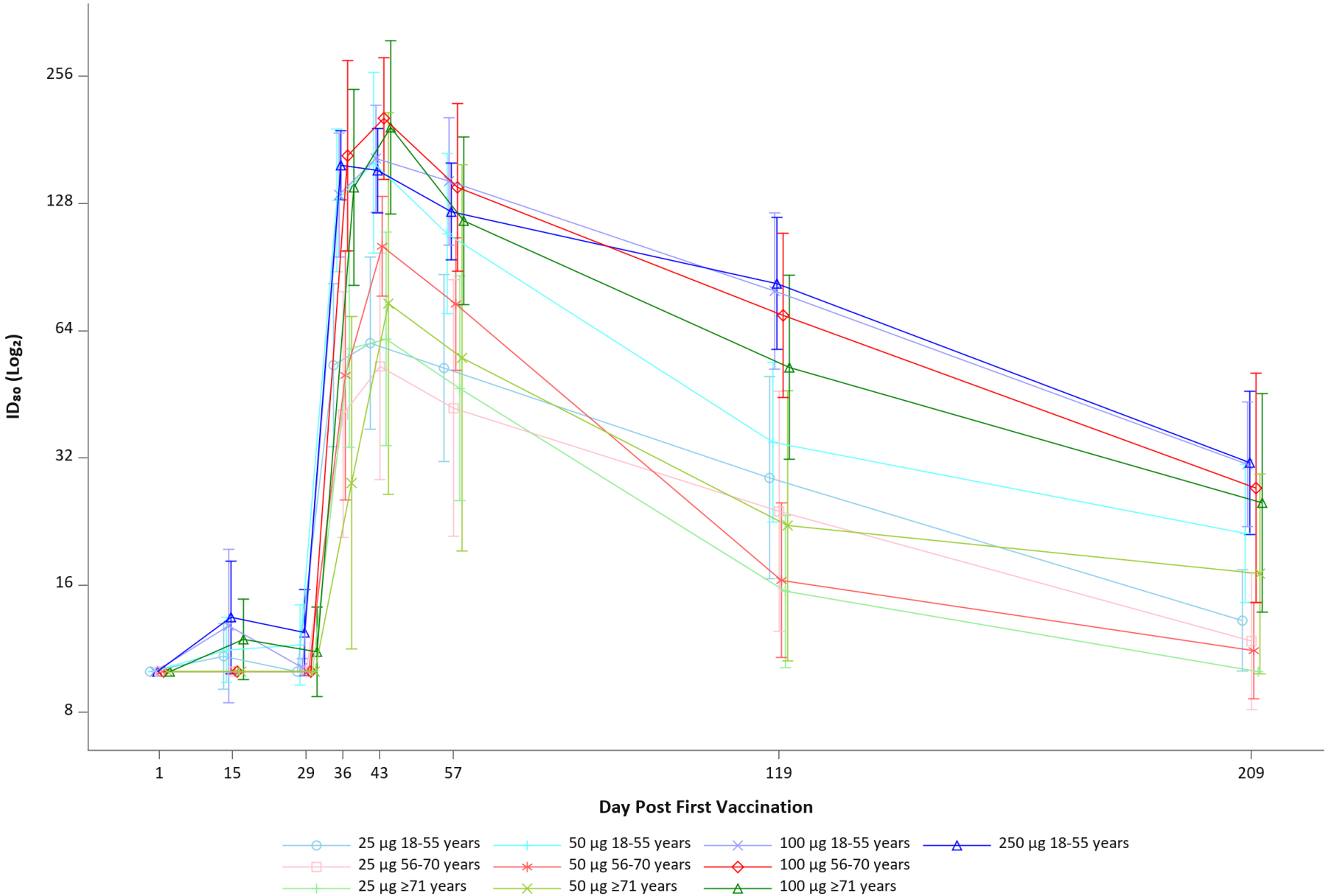

Figure 17: FRNT-mNG Geometric Mean by Time Point and Treatment Group - ID_{50}, Per Protocol Population

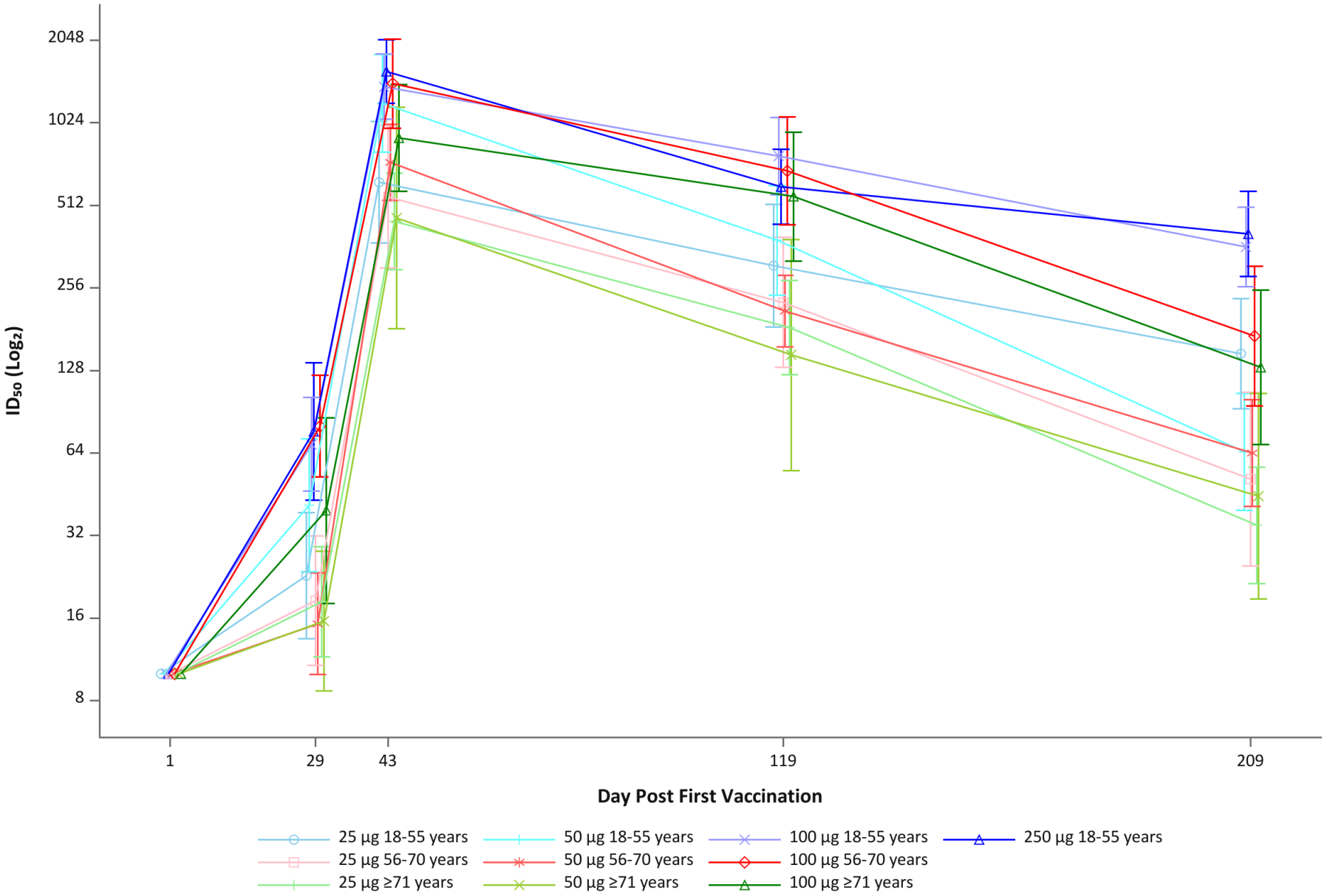

Figure 18: FRNT-mNG Geometric Mean by Time Point and Treatment Group - ID_{80}, Per Protocol Population

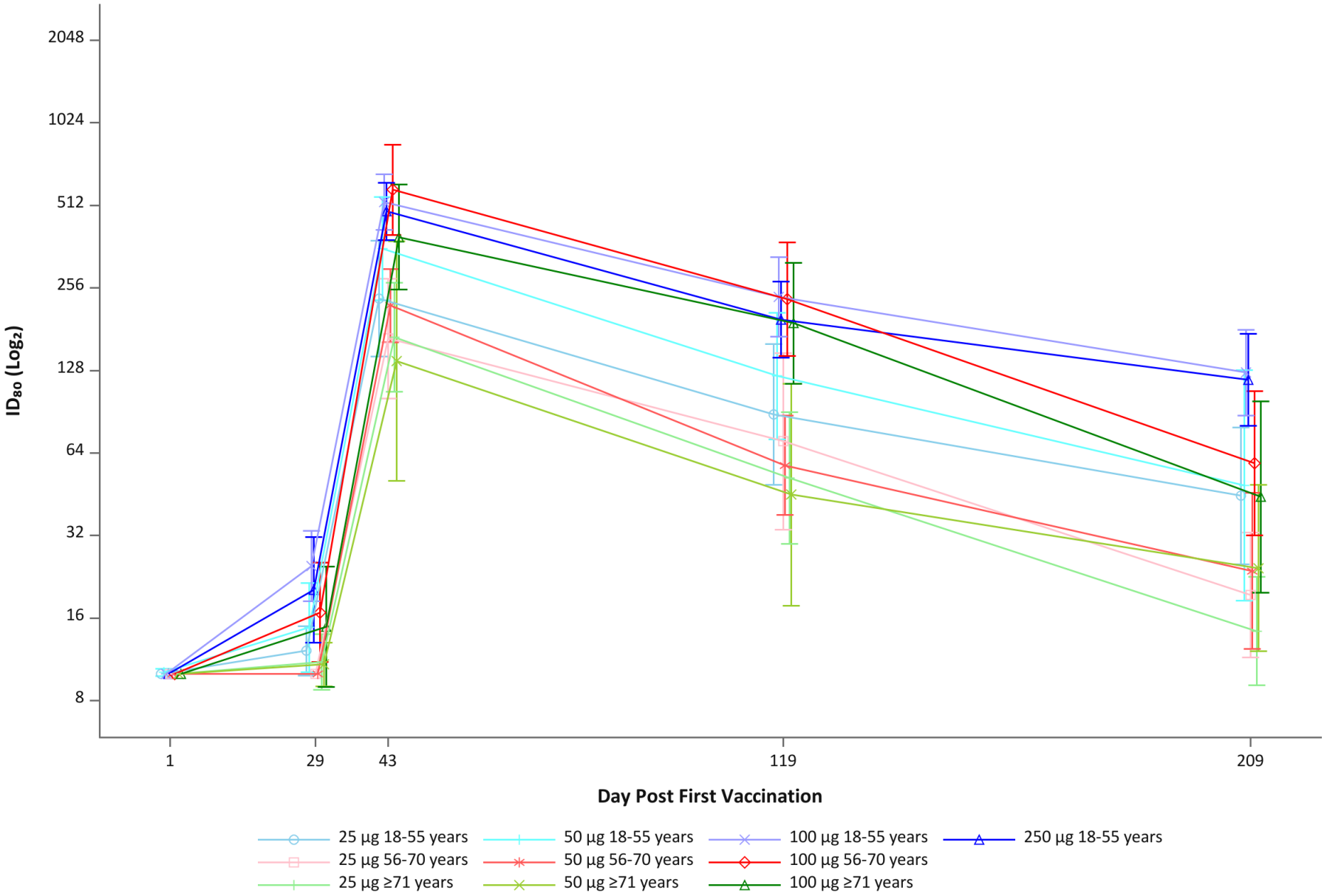

Figure 19: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age 18-55, Per Protocol Population

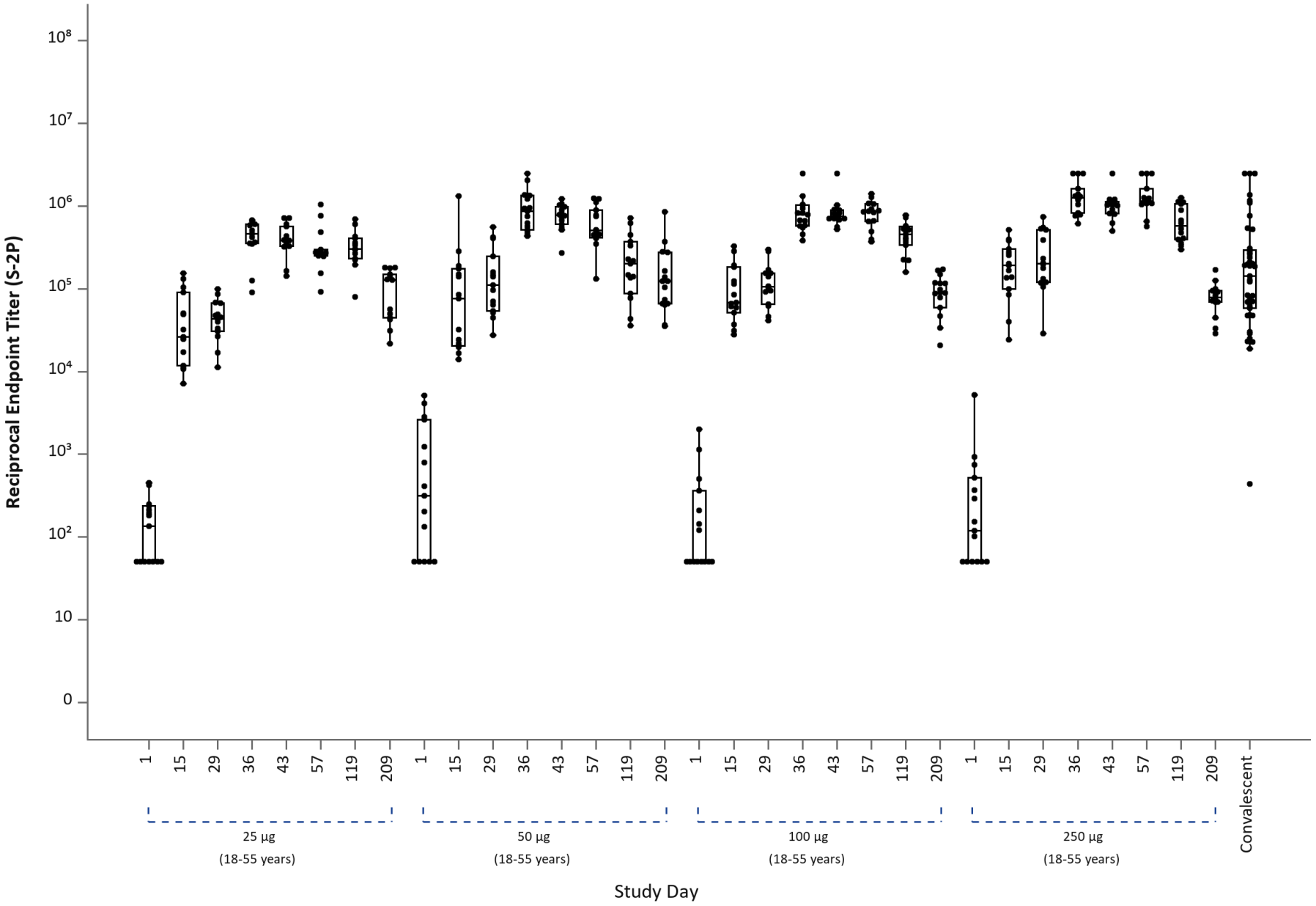

Figure 20: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age 56-70, Per Protocol Population

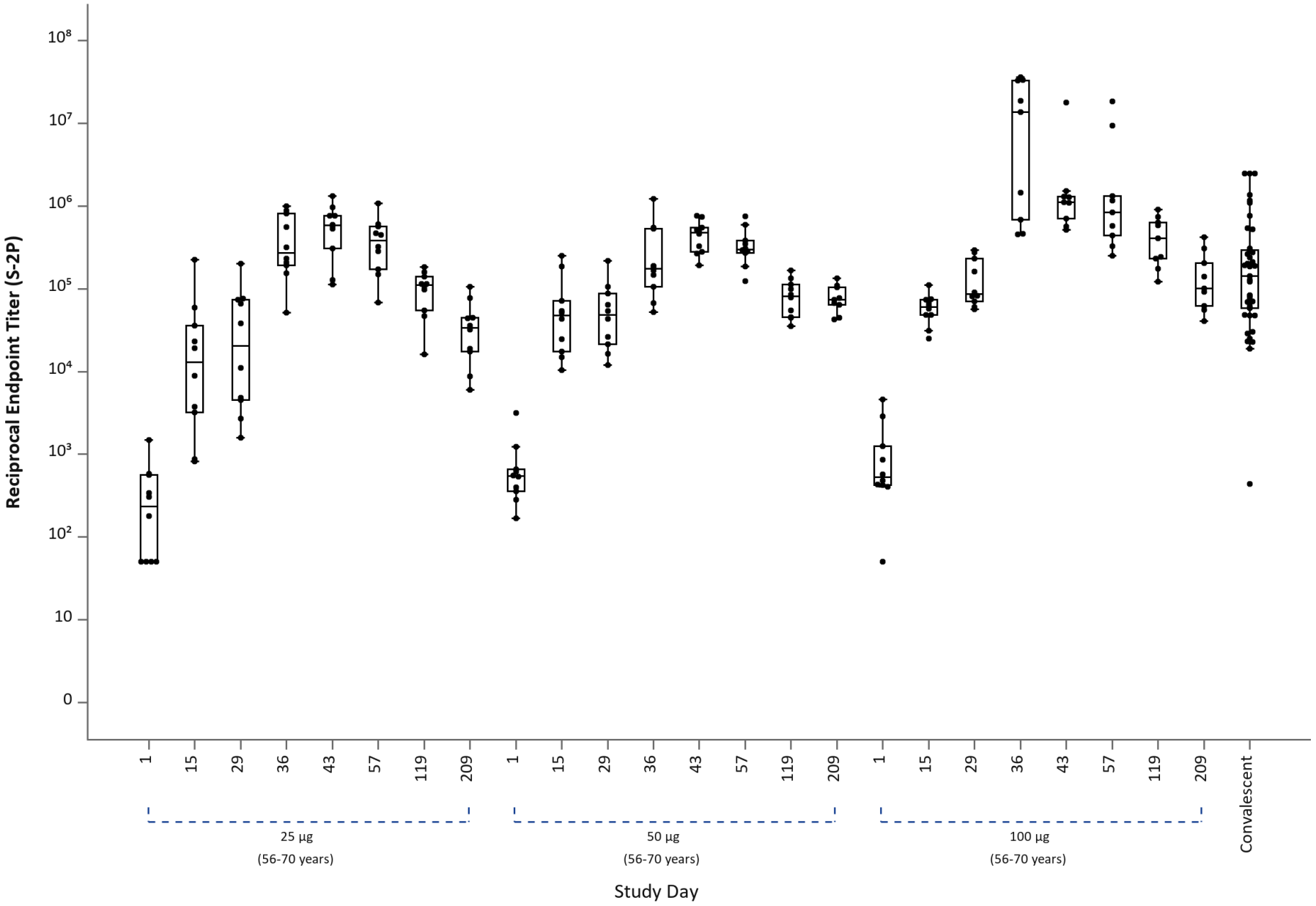

Figure 21: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - S-2P - Age ≥71, Per Protocol Population

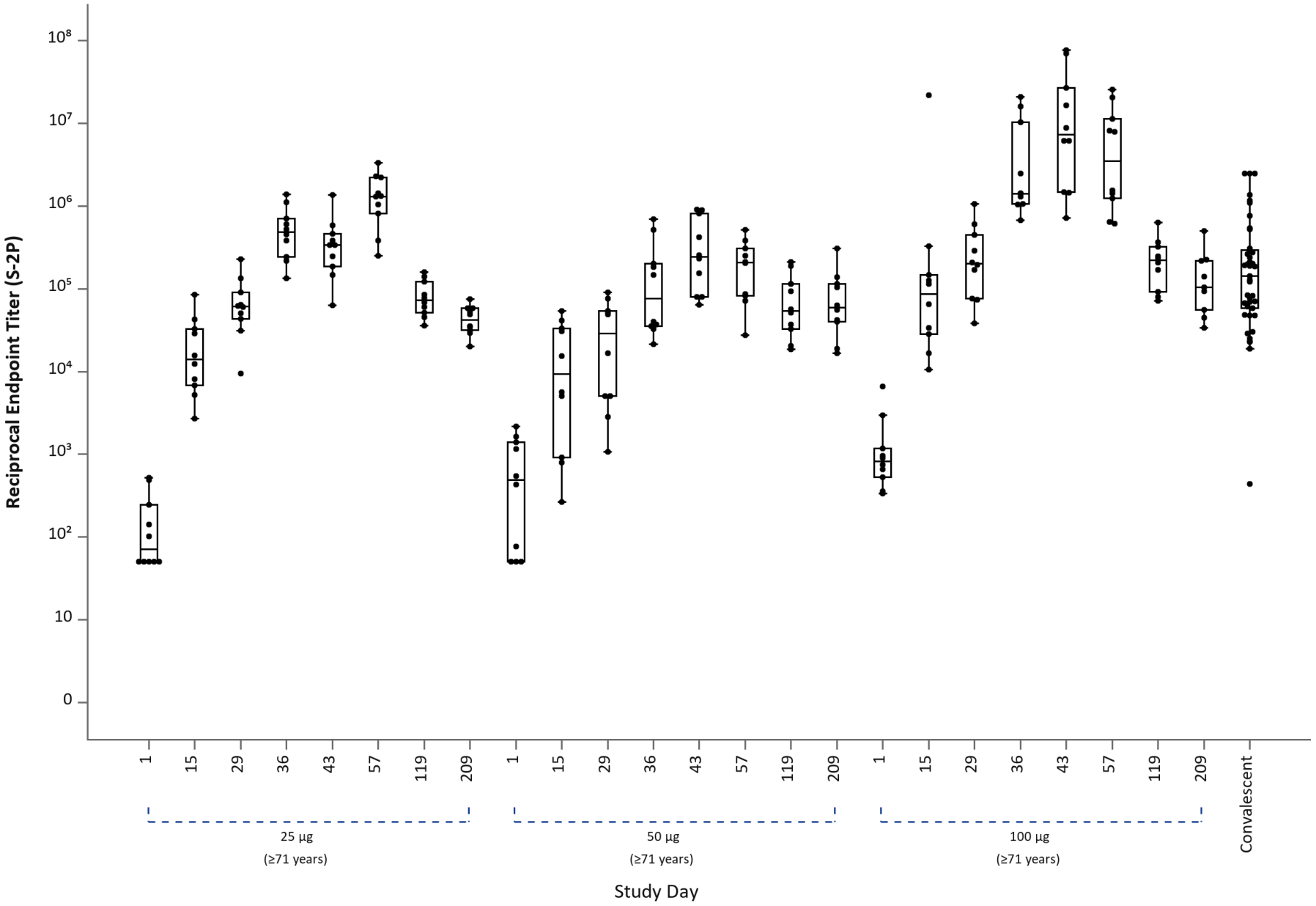

Figure 22: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age 18-55, Per Protocol Population

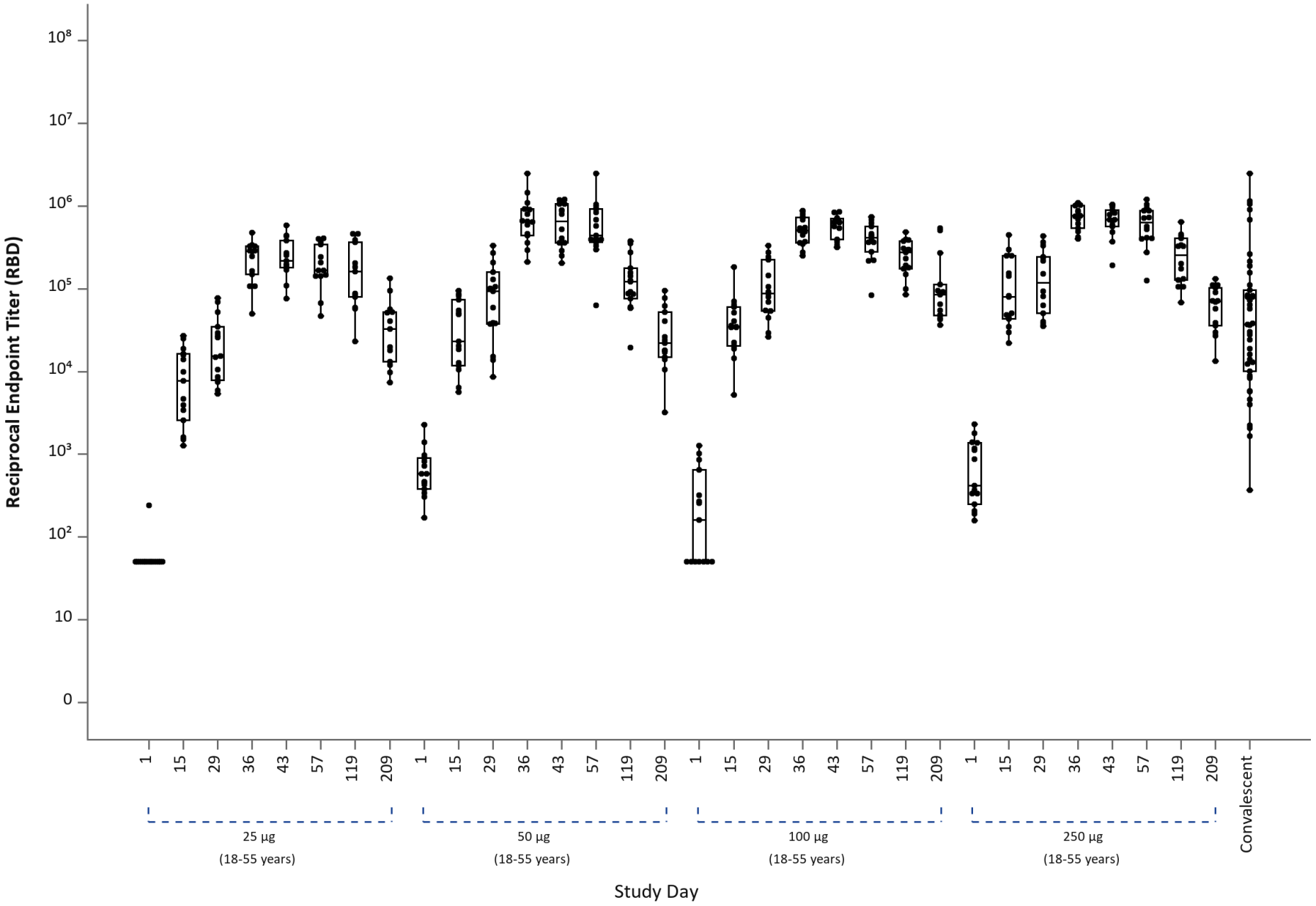

Figure 23: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age 56-70, Per Protocol Population

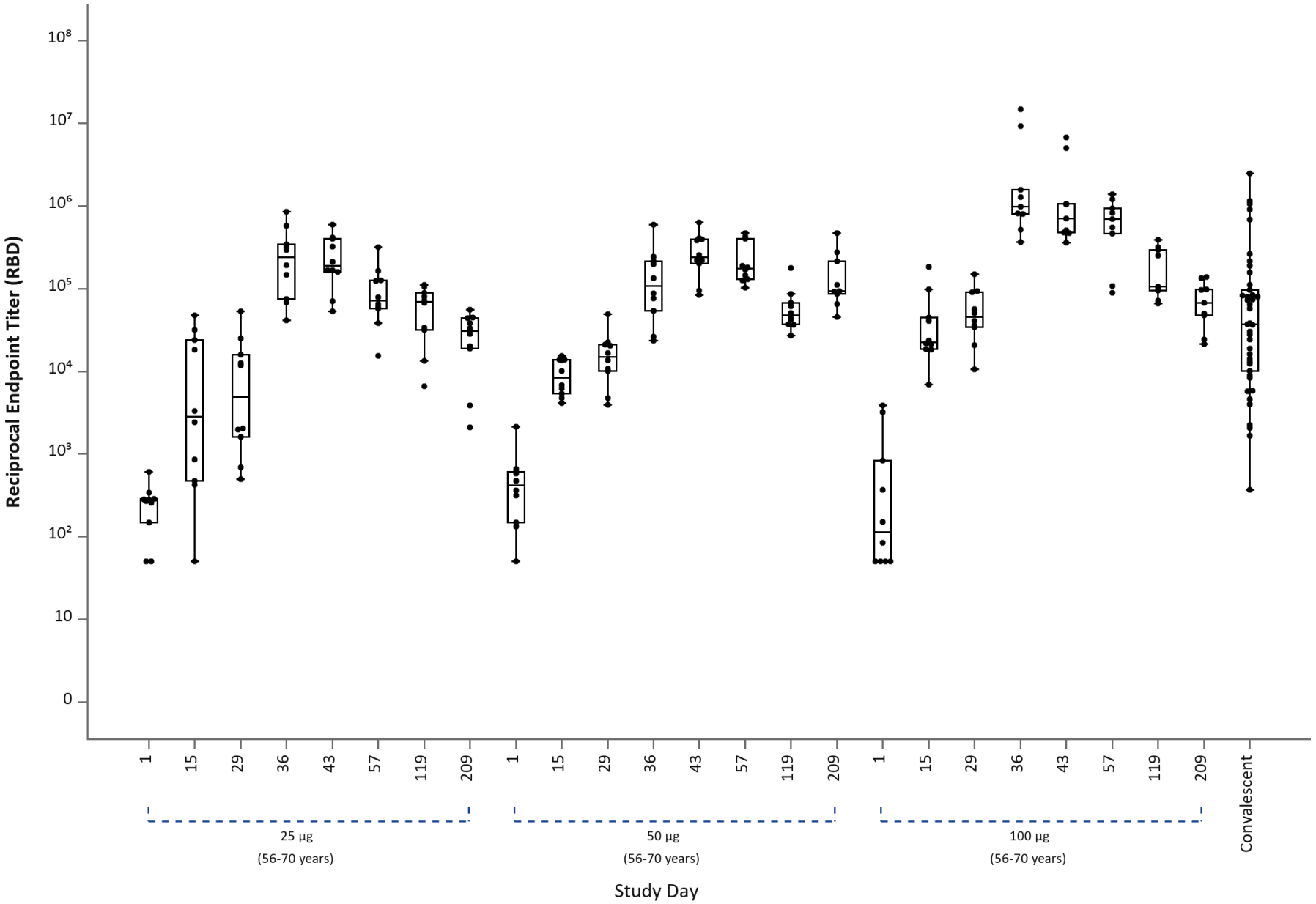

Figure 24: Serum IgG ELISA Endpoint Titer Distribution by Time Point and Treatment Group - RBD - Age ≥71, Per Protocol Population

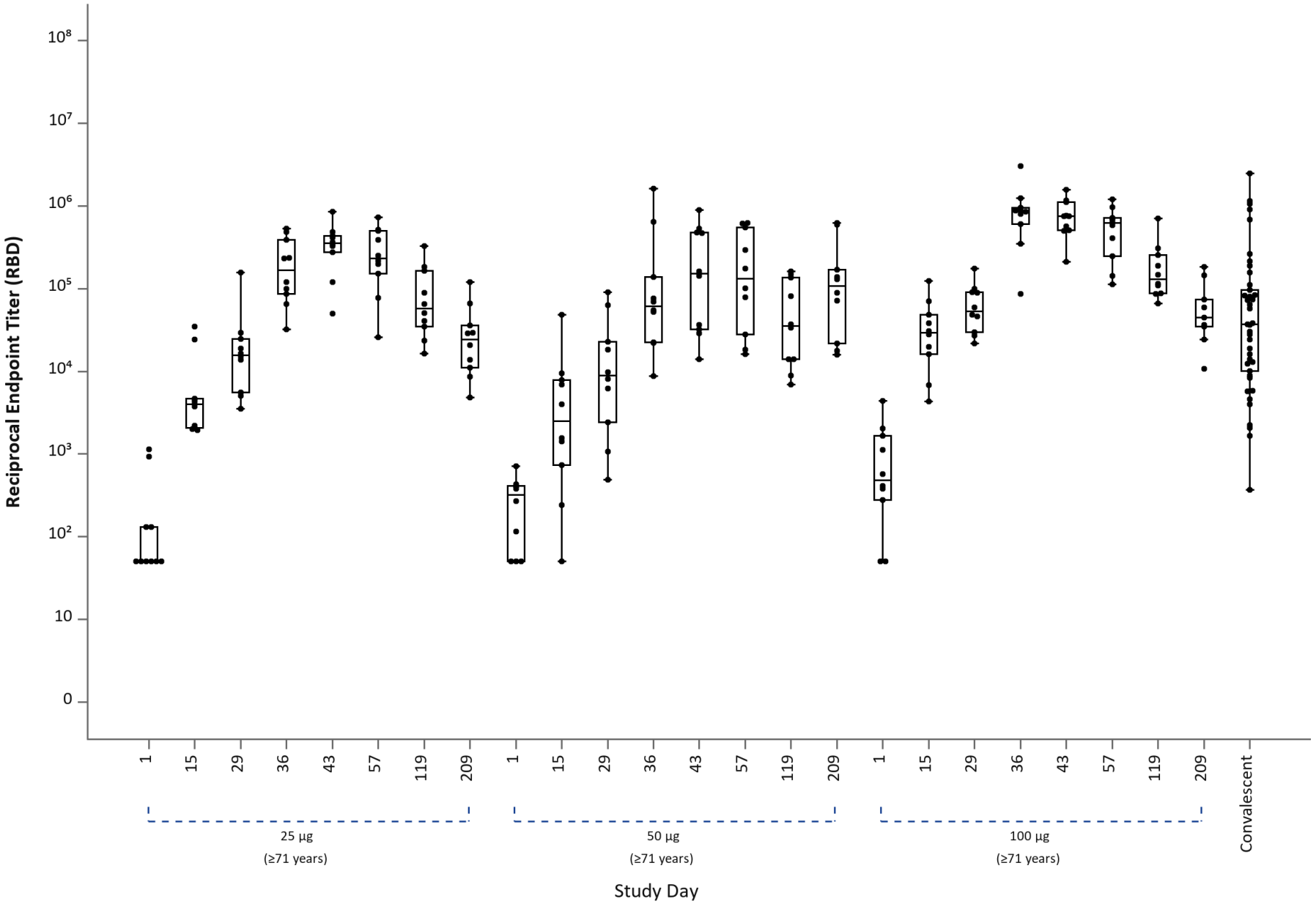

Figure 25: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age 18-55, Per Protocol Population

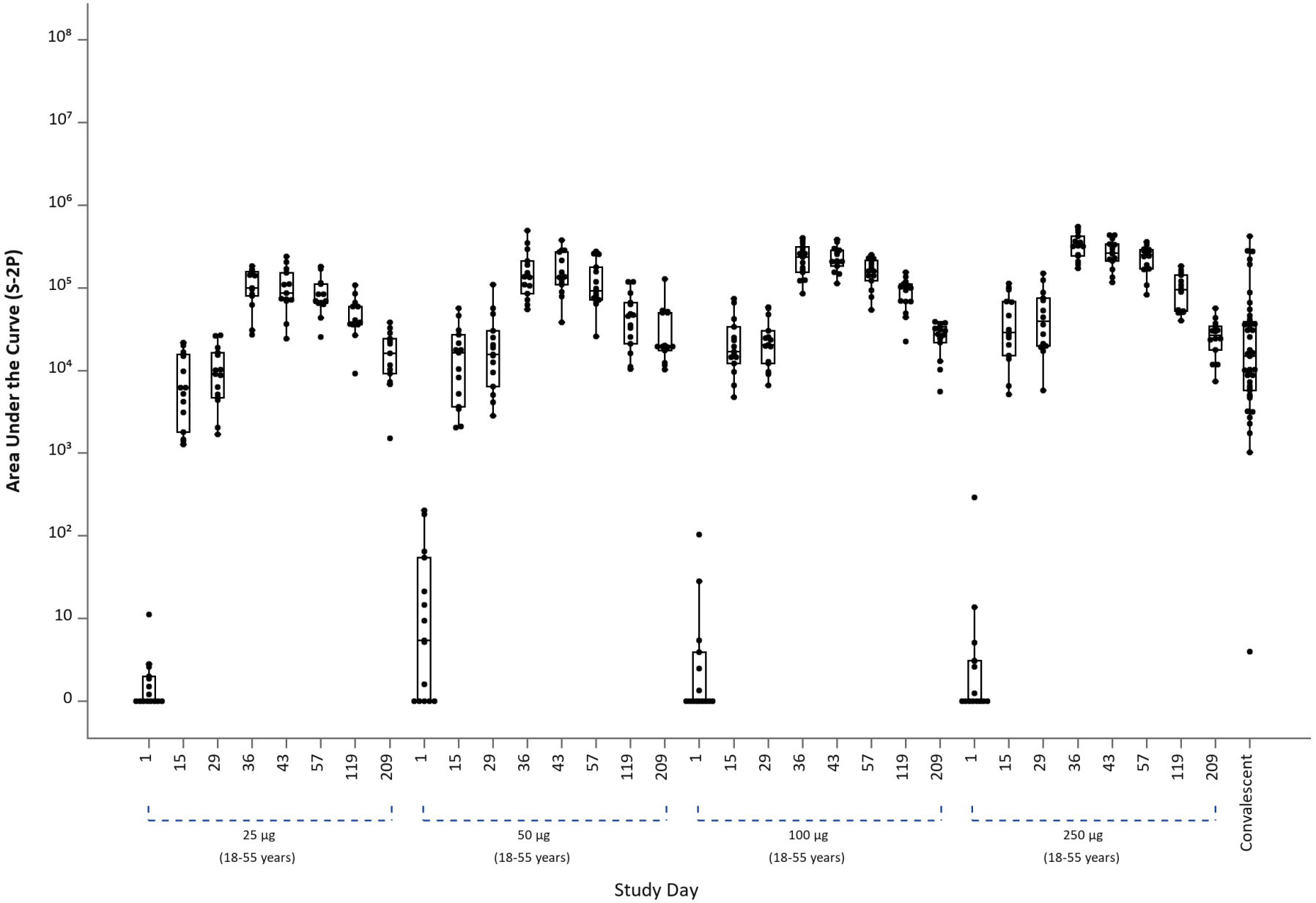

Figure 26: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age 56-70, Per Protocol Population

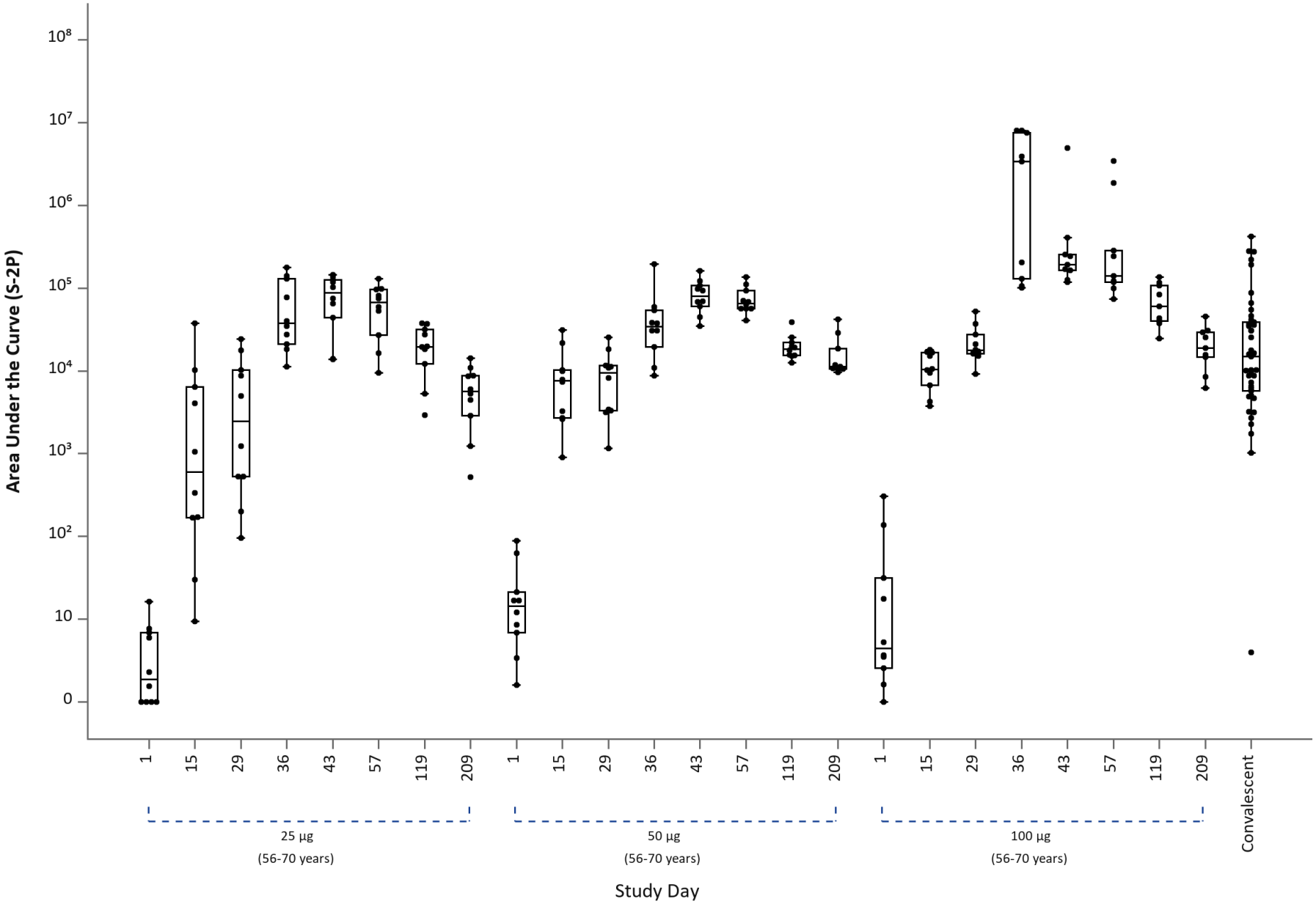

Figure 27: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - S-2P - Age ≥71, Per Protocol Population

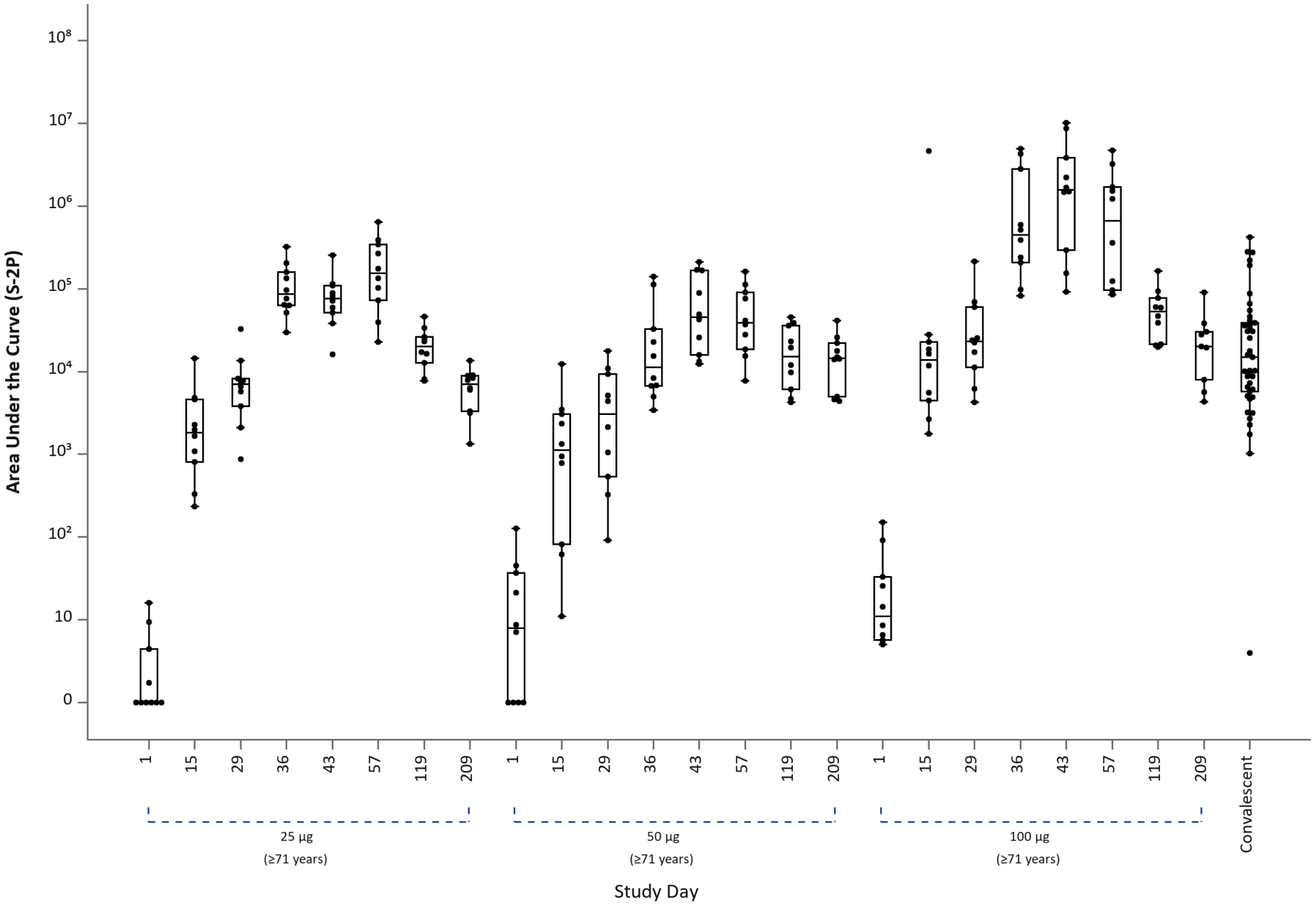

Figure 28: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age 18-55, Per Protocol Population

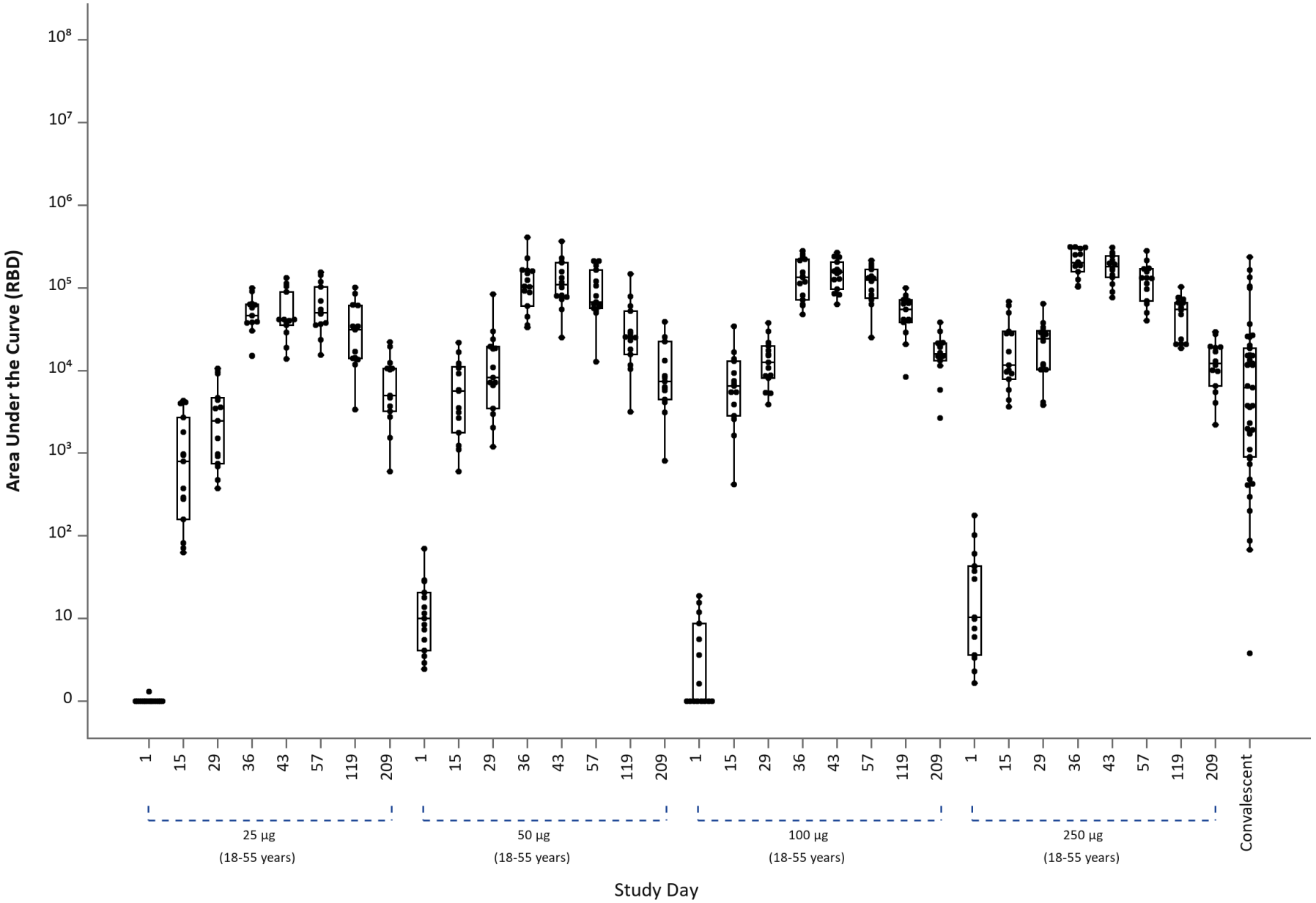

Figure 29: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age 56-70, Per Protocol Population

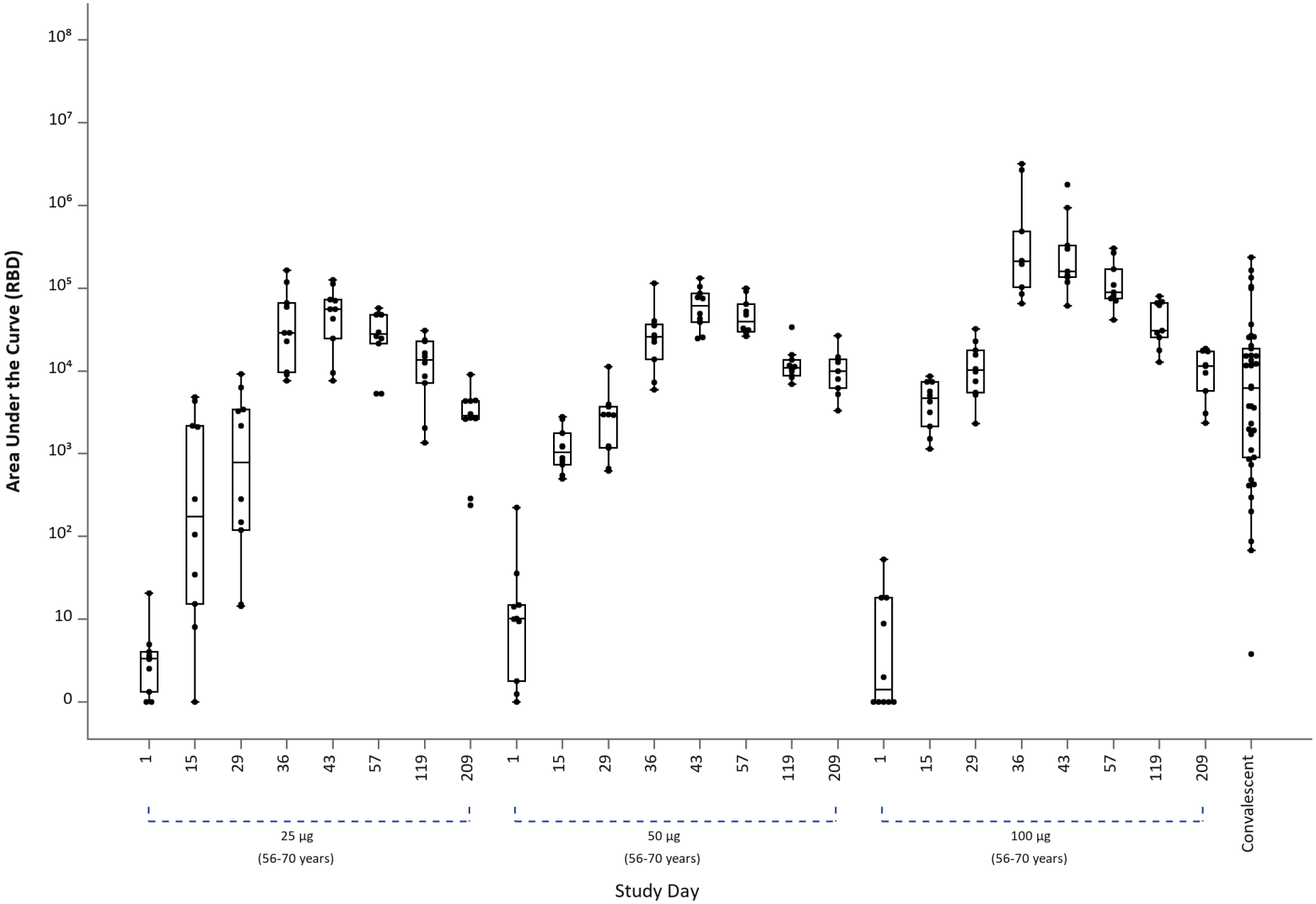

Figure 30: Serum IgG Area Under the Curve (AUC) Distribution by Time Point and Treatment Group - RBD - Age ≥71, Per Protocol Population

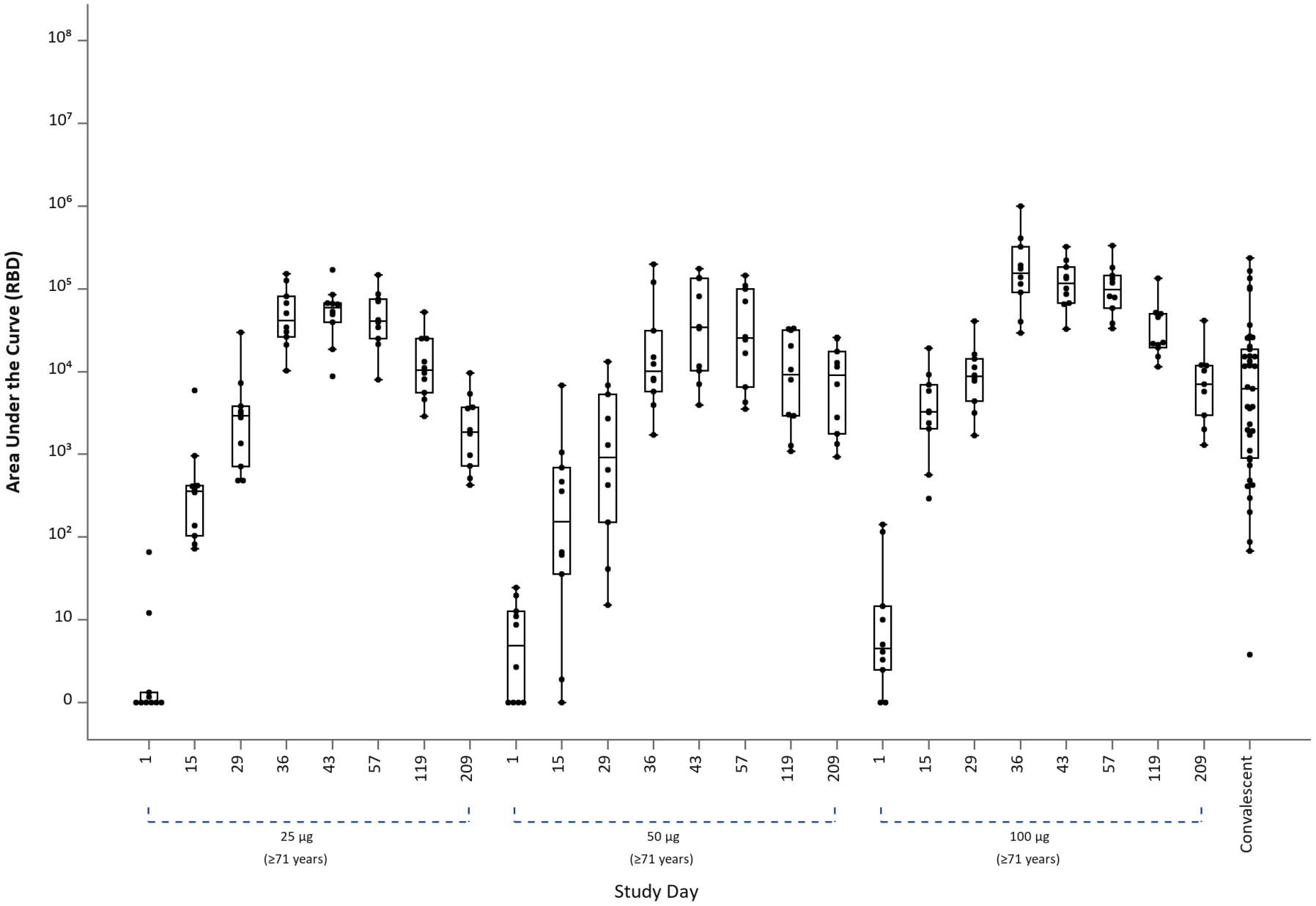

Figure 31: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 18-55, Per Protocol Population

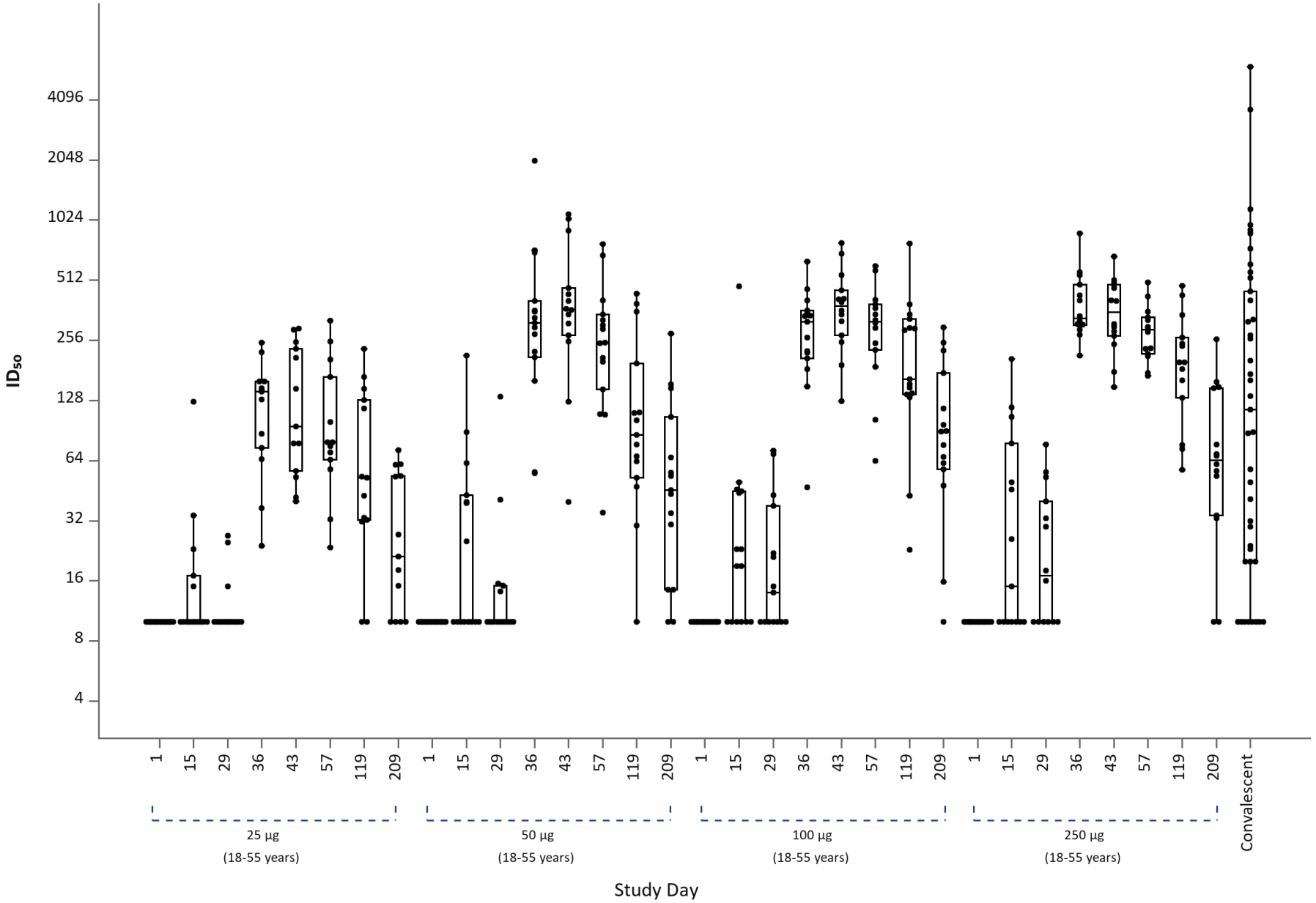

Figure 32: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 56-70, Per Protocol Population

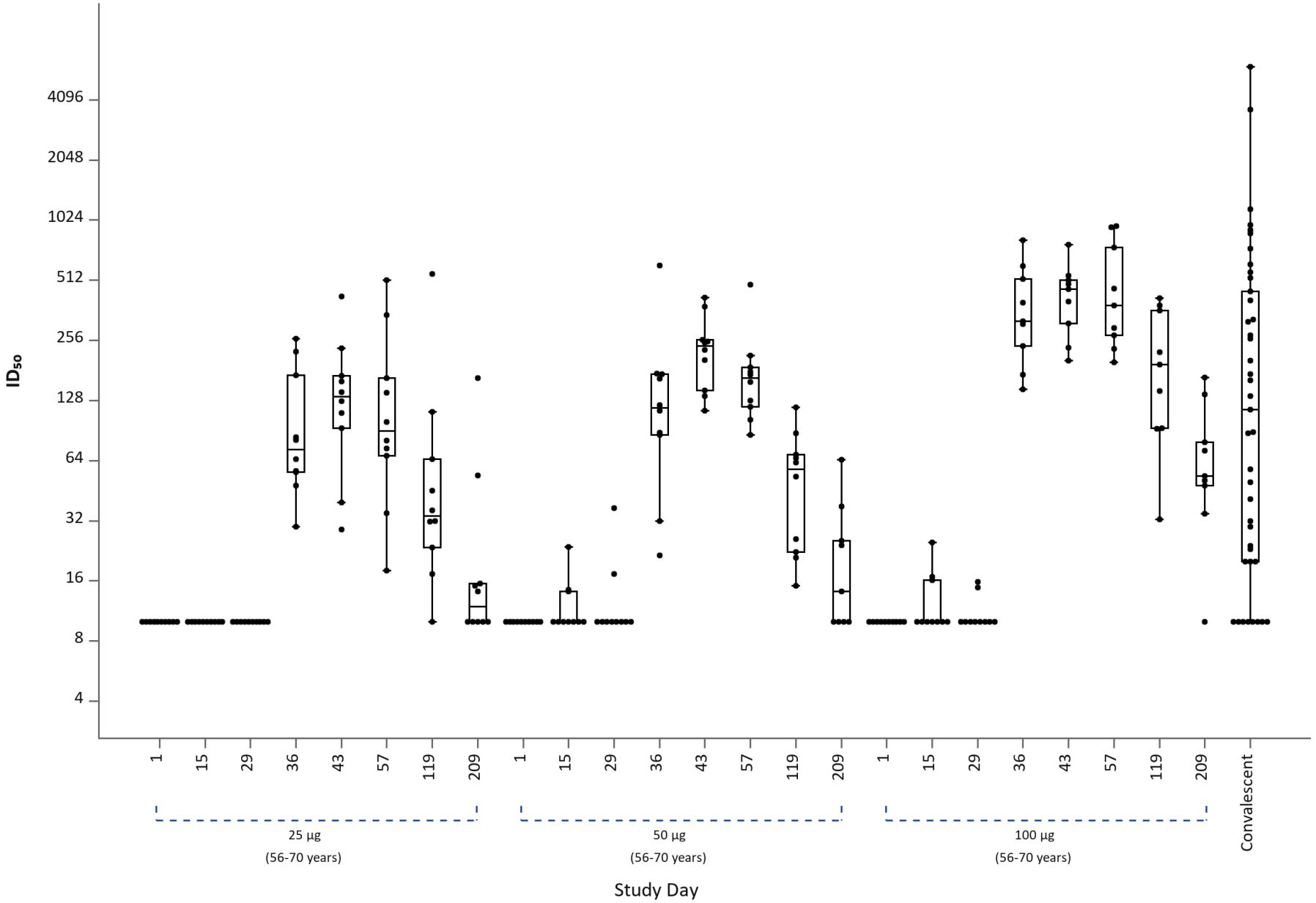

Figure 33: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{50} - Age ≥71, Per Protocol Population

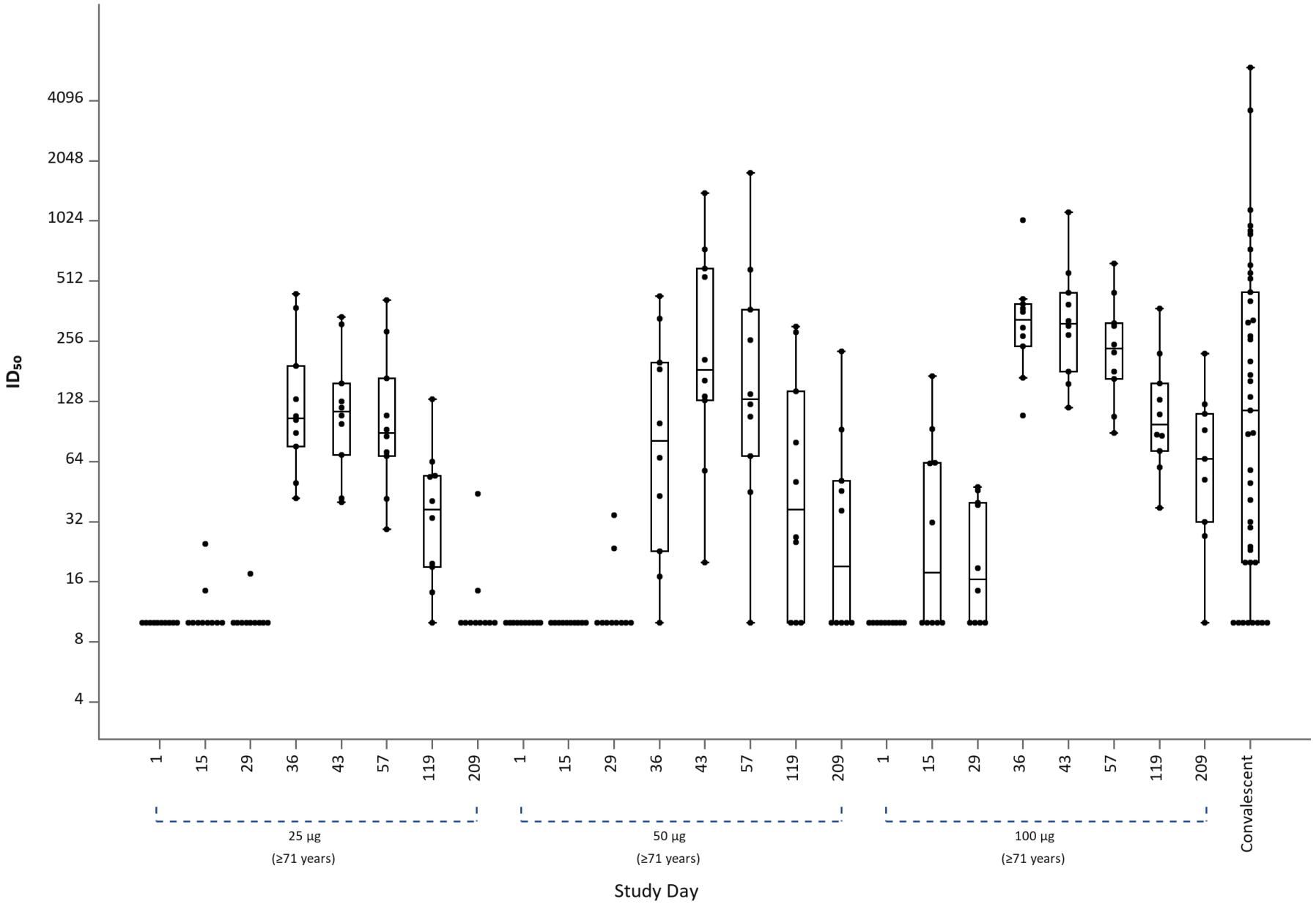

Figure 34: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 18-55, Per Protocol Population

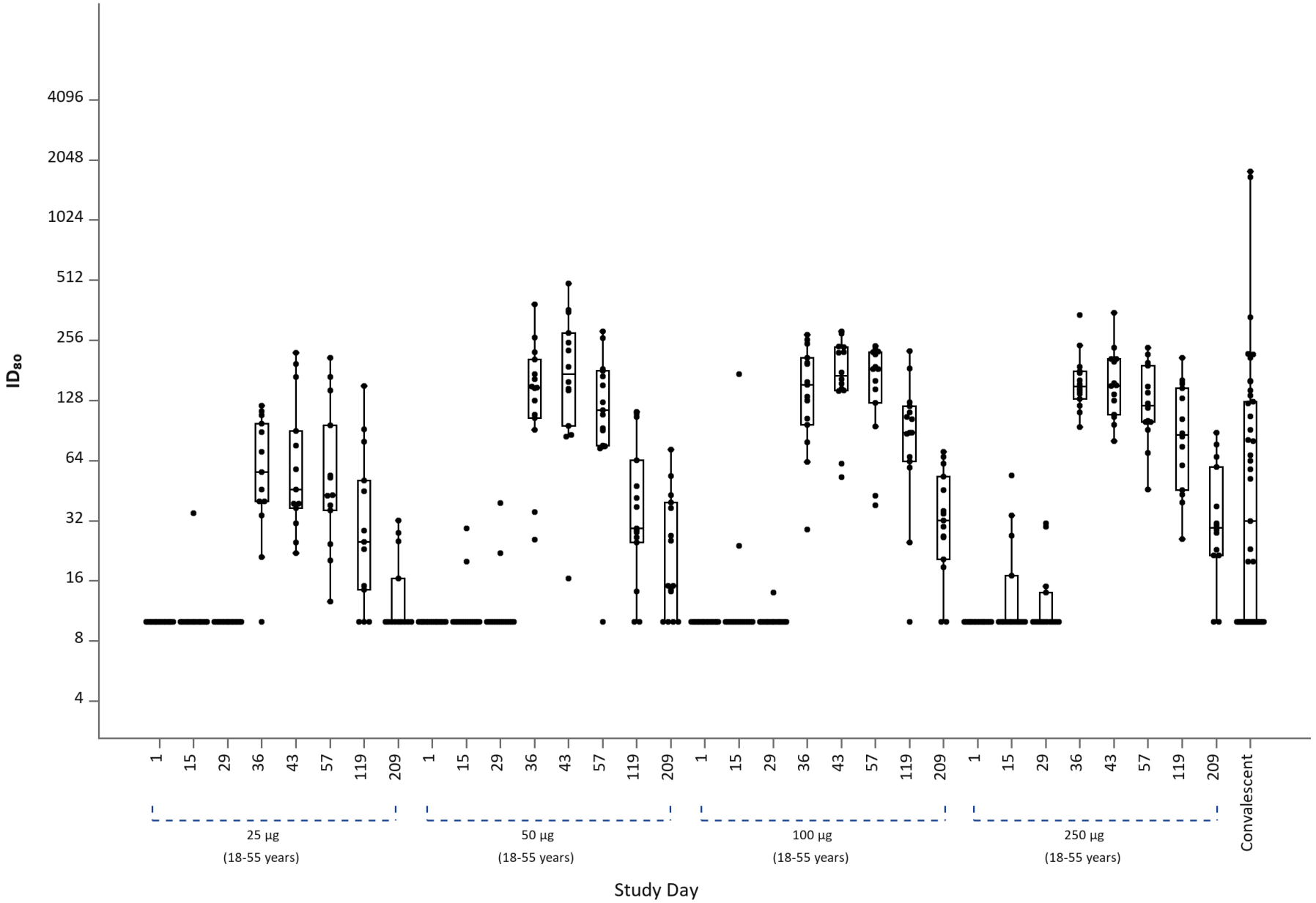

Figure 35: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 56-70, Per Protocol Population

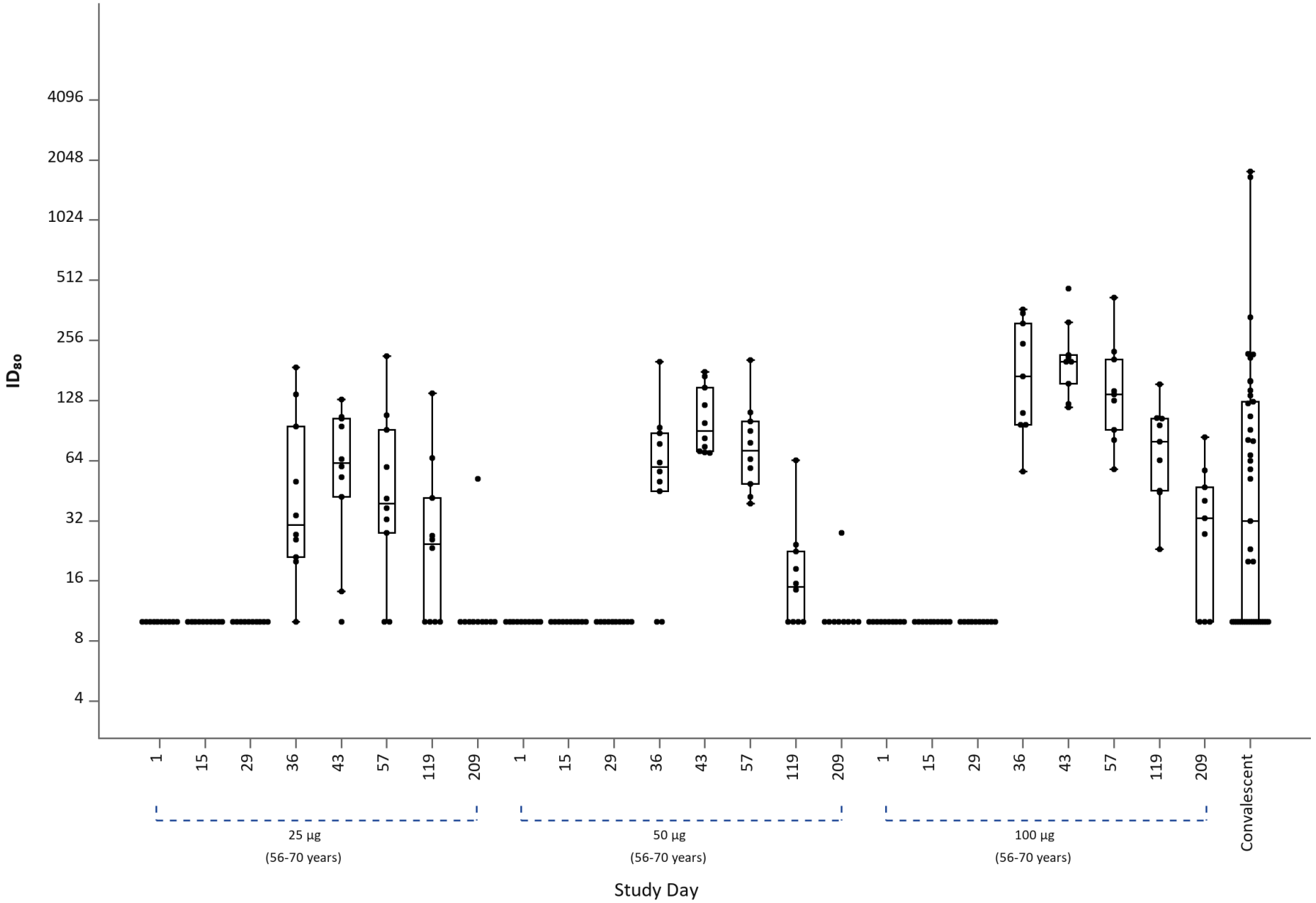

Figure 36: Pseudovirus Neutralization Assay Titers Distribution by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

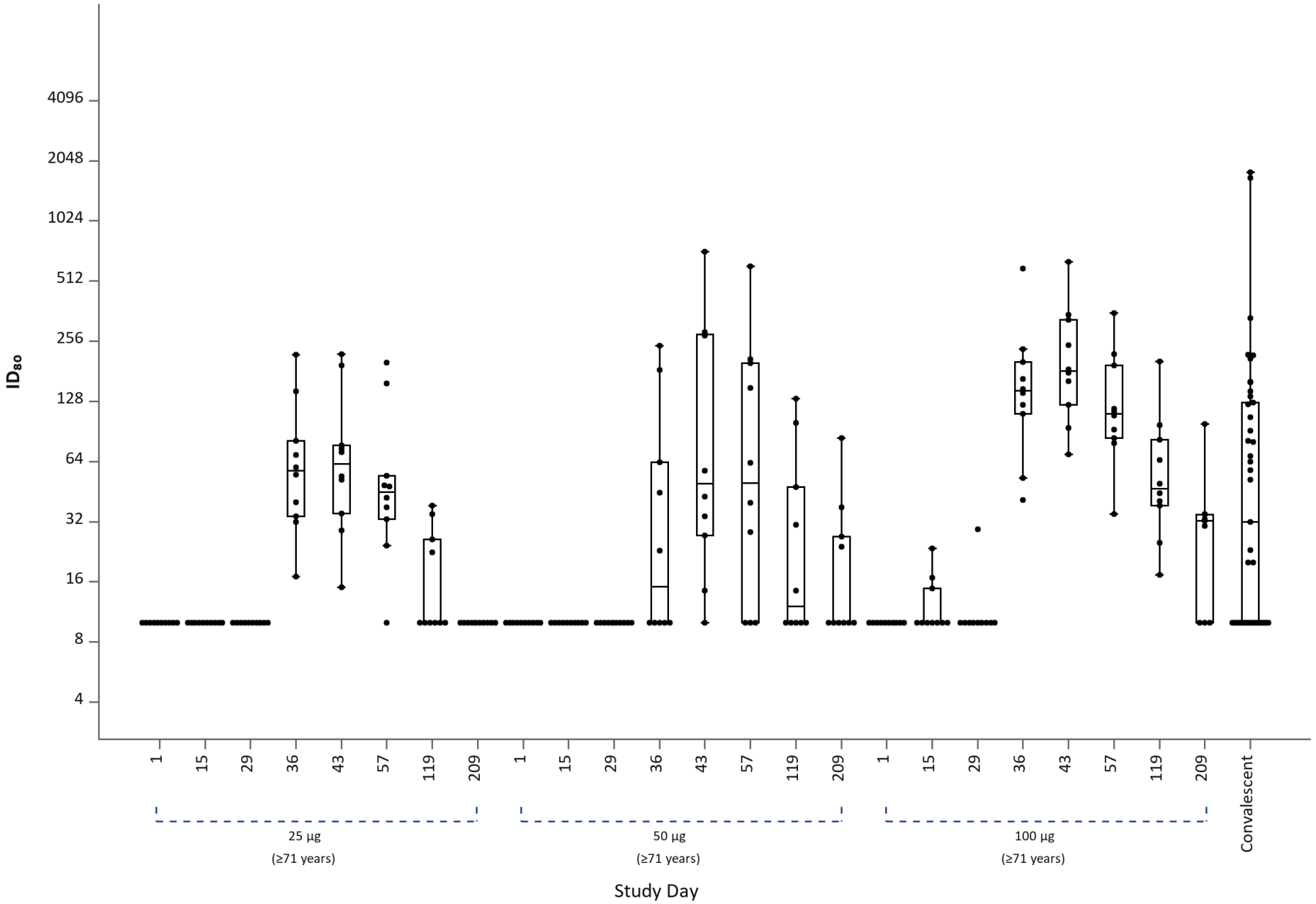

Figure 37: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 18-55, Per Protocol Population

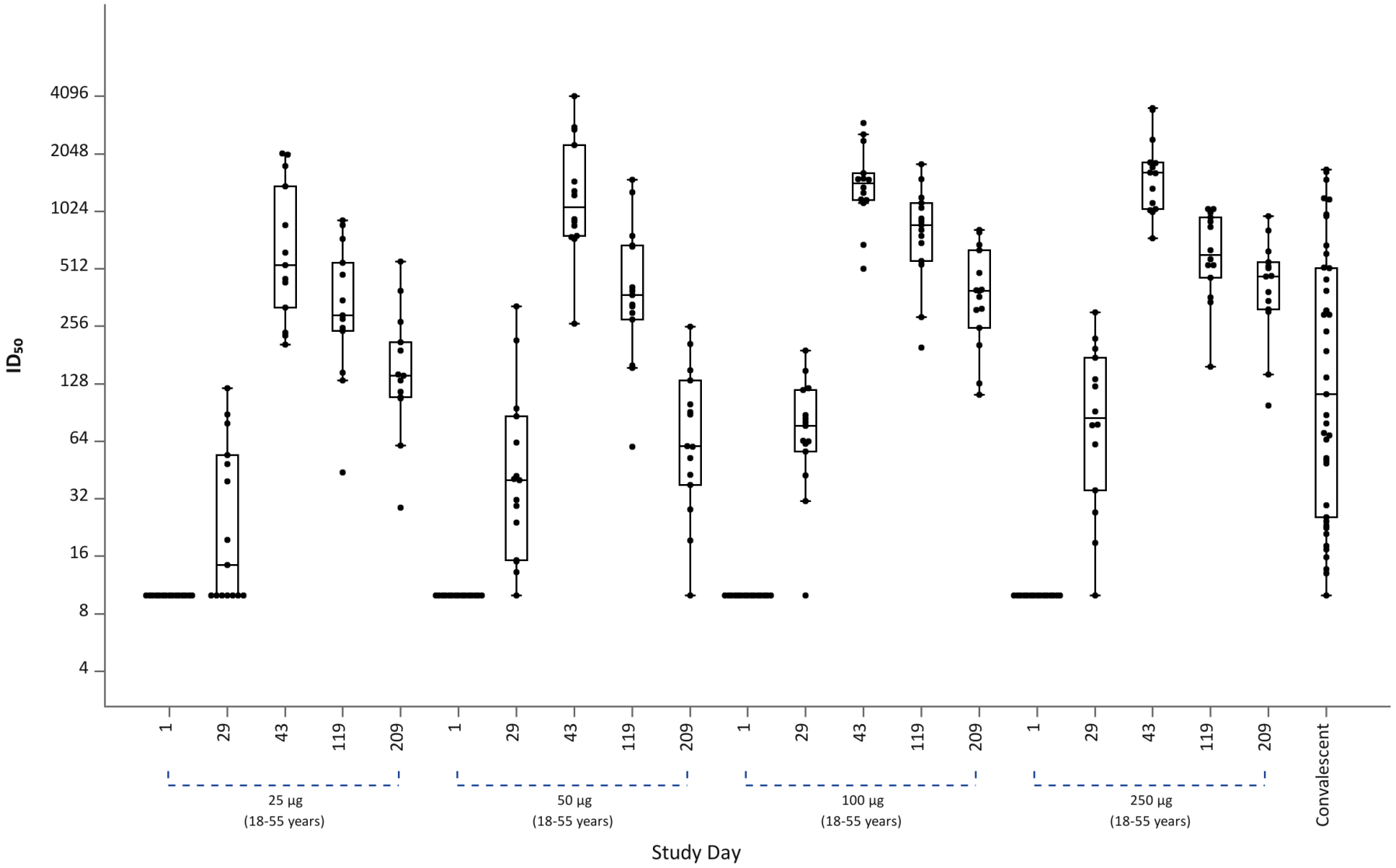

Figure 38: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age 56-70, Per Protocol Population

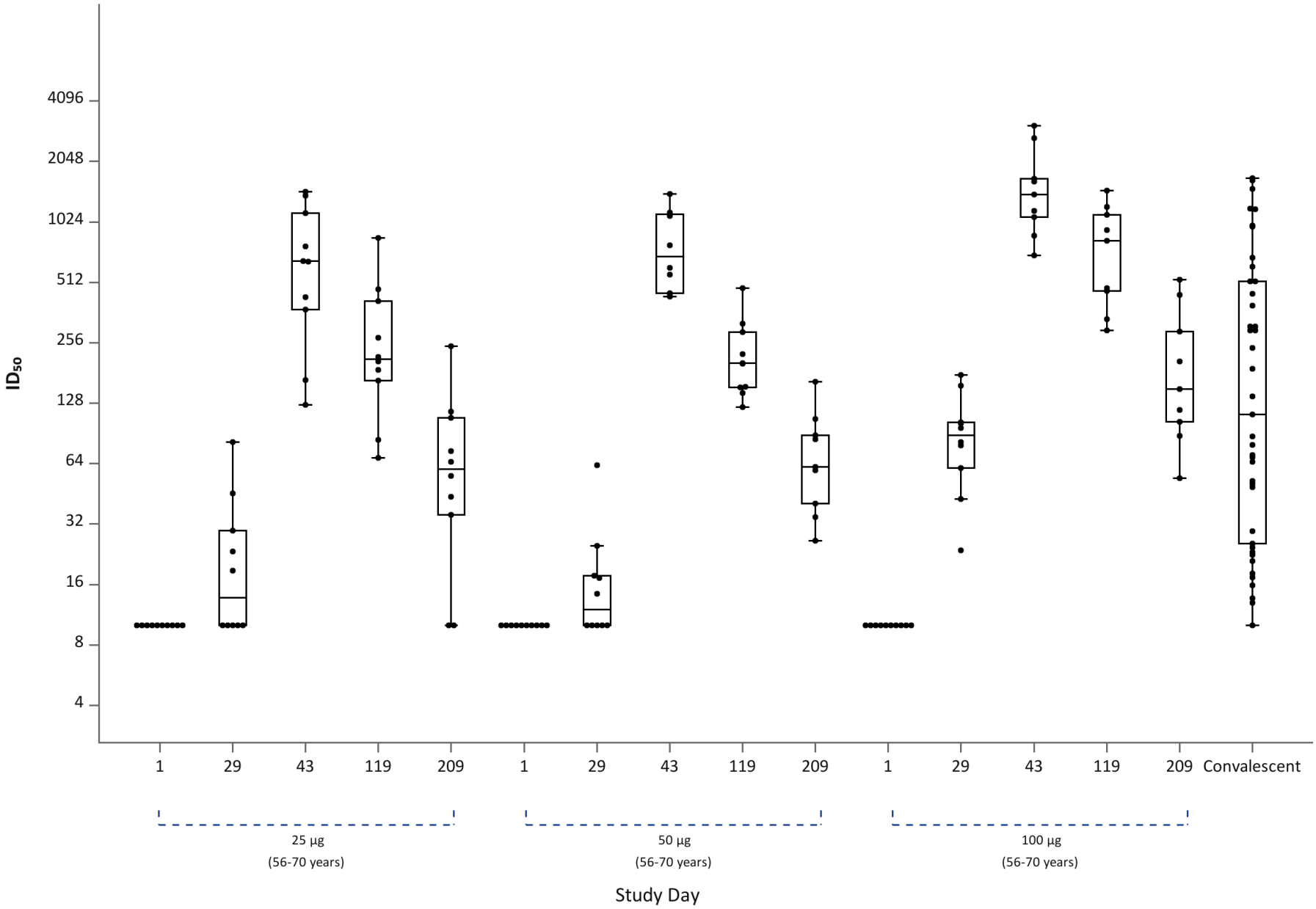

Figure 39: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{50} - Age ≥71, Per Protocol Population

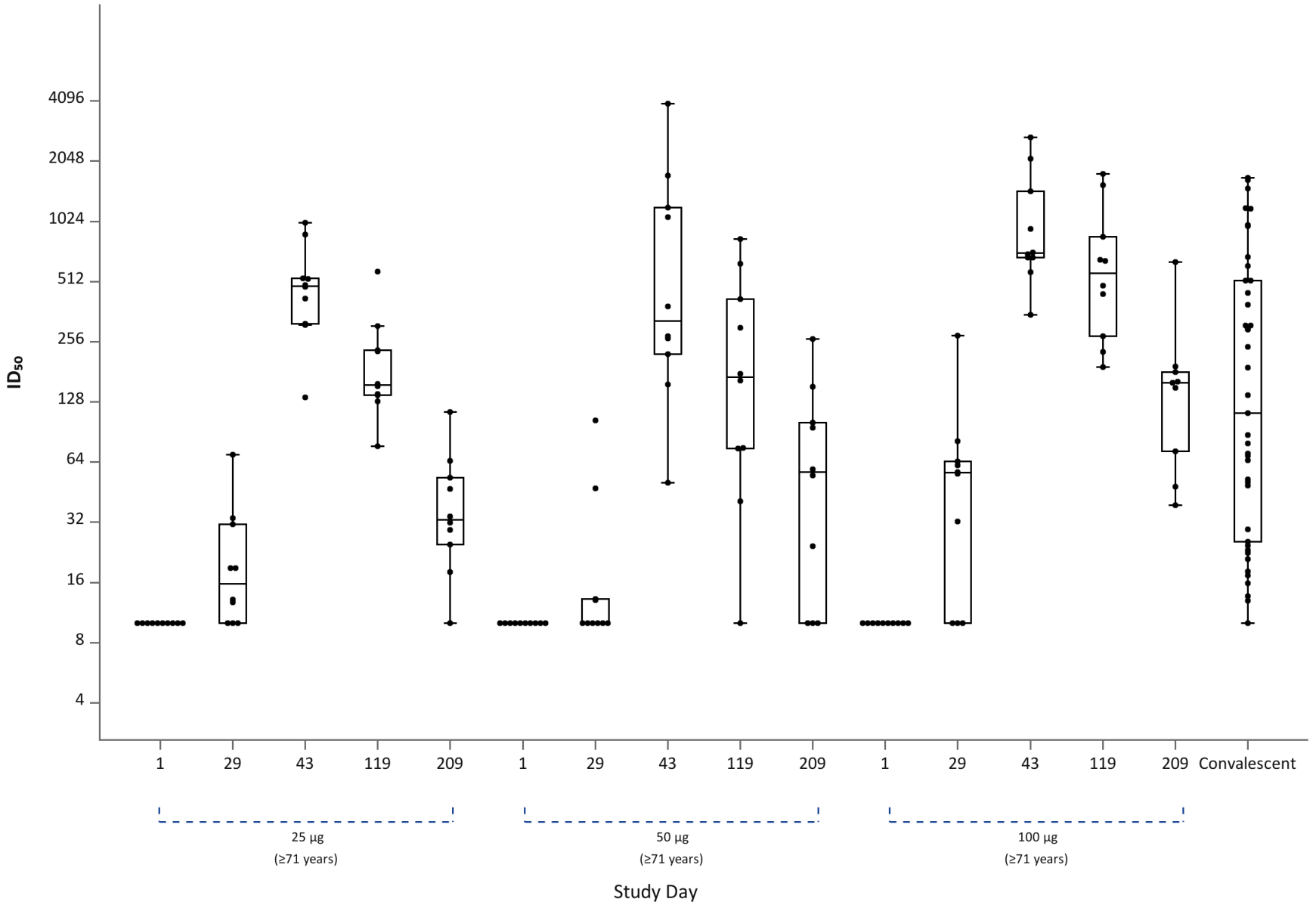

Figure 40: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 18-55, Per Protocol Population

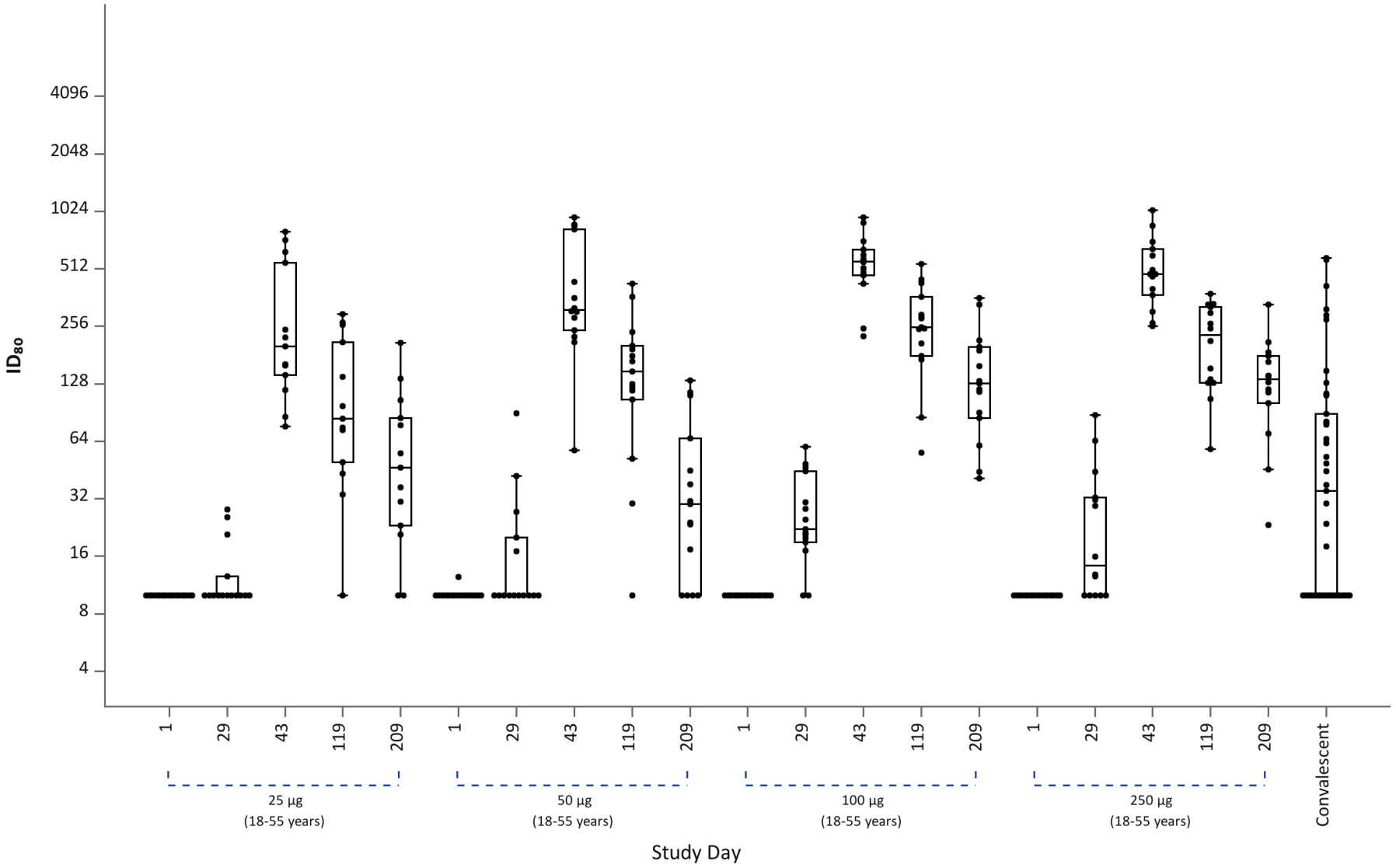

Figure 41: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age 56-70, Per Protocol Population

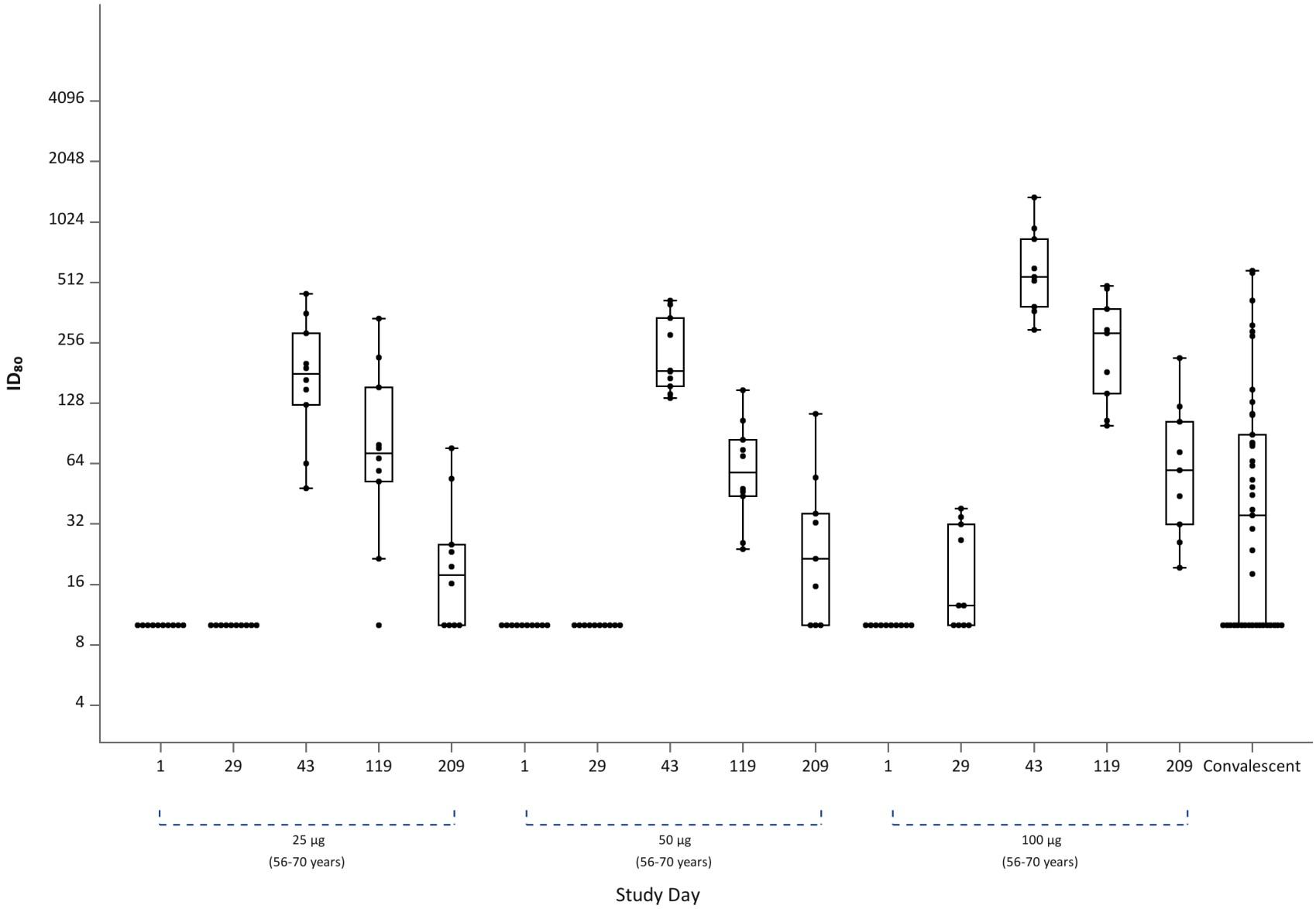

Figure 42: FRNT-mNG Titers Distribution by Time Point and Treatment Group - ID_{80} - Age ≥71, Per Protocol Population

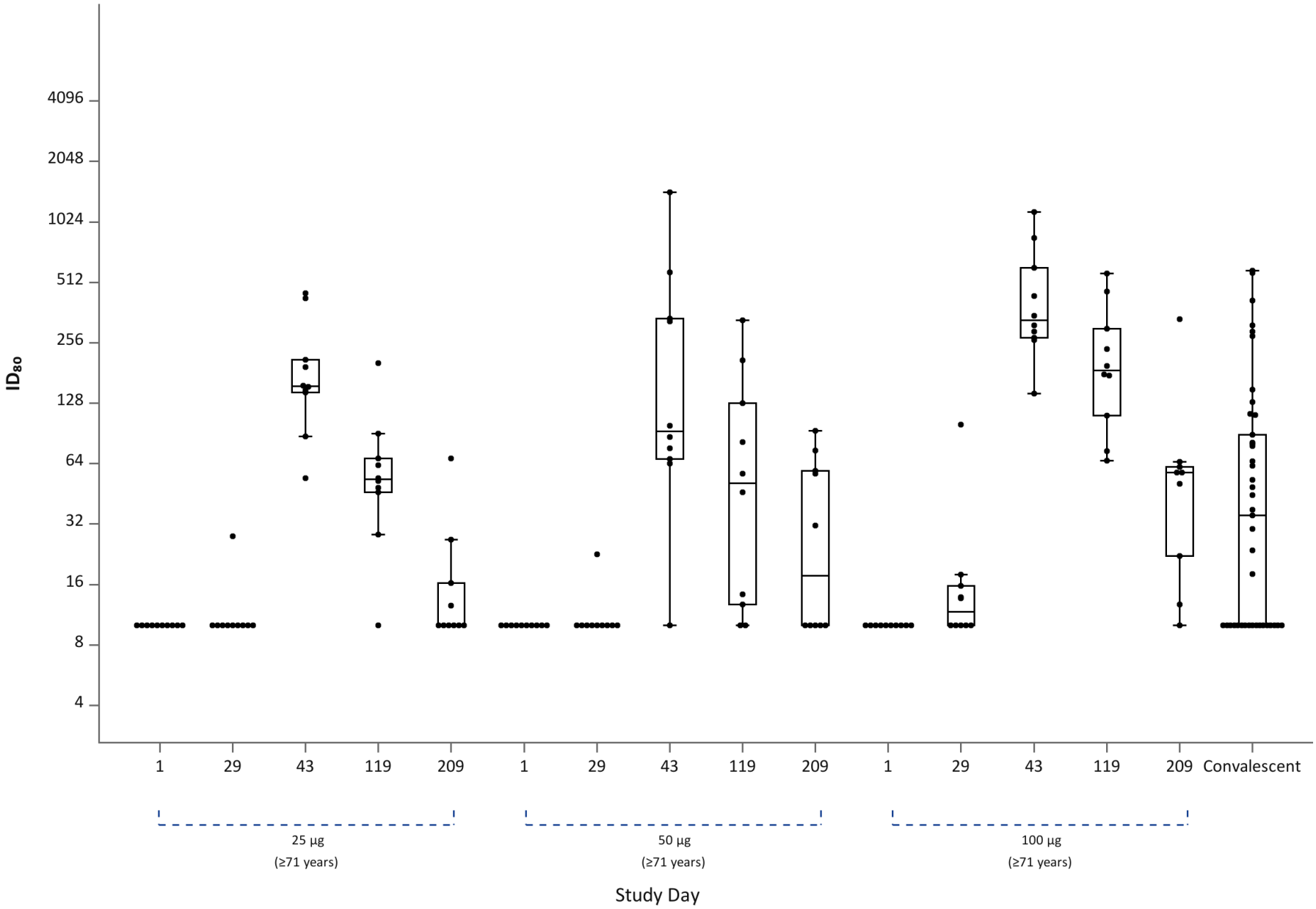

TABLE 37:
All Adverse Events Cross-Classified by
MedDRA® System Organ Class, Severity, and Relationship to Study Treatment, and
Treatment Group – 25 µg mRNA-1273 18-55 years (N=15)

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Any SOC	**Mild**	26	4	.
	Moderate	3	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**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	1	.	.
	Moderate	1	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	Mild	8	.	.
	Moderate	1	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	1	.	.
	Moderate	.	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary 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	3	2	.
	Moderate	.	.	.
	Severe	.	.	.
Vascular Disorders	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 38:
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**	16	6	.
	Moderate	7	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	3	1	.
	Severe	.	.	.
General Disorders And Administration Site Conditions	**Mild**	2	1	.
	Moderate	.	.	.
	Severe	.	.	.
Immune System Disorders	**Mild**	1	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	1	.	.
	Moderate	1	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	Mild	3	.	.
	Moderate	.	.	.
	Severe	.	.	.
Investigations	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Musculoskeletal And Connective Tissue Disorders	Mild	1	1	.
	Moderate	2	.	.
	Severe	.	.	.
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Nervous System Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Psychiatric Disorders	Mild	.	.	.
	Moderate	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Reproductive System And Breast Disorders	Mild	1	.	.
	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 39:
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	5	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**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	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	.	.	.
	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	2	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	.	.	.
	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 40:
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**	16	9	.
	Moderate	10	7	.
	Severe	1	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**	4	2	.
	Moderate	1	.	.
	Severe	1	.	.
General Disorders And Administration Site Conditions	**Mild**	1	2	.
	Moderate	.	2	.
	Severe	.	.	.
Immune System Disorders	**Mild**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	2	.	.
	Moderate	1	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	Mild	.	.	.
	Moderate	1	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	.	1	.
	Moderate	1	2	.
	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	1	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Reproductive System And Breast Disorders	Mild	1	1	.
	Moderate	1	.	.
	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 41:
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**	72	27	.
	Moderate	25	11	.
	Severe	1	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**	9	2	.
	Moderate	5	3	.
	Severe	1	.	.
General Disorders And Administration Site Conditions	**Mild**	12	6	.
	Moderate	.	3	.
	Severe	.	.	.
Immune System Disorders	**Mild**	1	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	**Mild**	4	.	.
	Moderate	5	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	**Mild**	13	.	.
	Moderate	3	.	.
	Severe	.	.	.
Investigations	**Mild**	2	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	**Mild**	1	3	.
	Moderate	1	2	.
	Severe	.	.	.
Musculoskeletal And Connective Tissue Disorders	**Mild**	4	3	.
	Moderate	3	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	3	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Reproductive System And Breast Disorders	Mild	3	1	.
	Moderate	1	.	.
	Severe	.	.	.
Respiratory, Thoracic And Mediastinal Disorders	Mild	7	4	.
	Moderate	1	.	.
	Severe	.	.	.
Skin And Subcutaneous Tissue Disorders	Mild	4	2	.
	Moderate	.	2	.
	Severe	.	.	.
Vascular Disorders	Mild	3	1	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 42:
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	10	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
	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**	1	.	.
	Moderate	.	1	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary 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	3	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 43:
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**	5	.	.
	Moderate	4	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	1	.
	Severe	.	.	.
General Disorders And Administration Site Conditions	**Mild**	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Immune System Disorders	**Mild**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	.	.	.
	Moderate	2	.	.
	Severe	1	.	.
Injury, Poisoning And Procedural Complications	Mild	2	.	.
	Moderate	1	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	.	.	.
	Moderate	.	.	.
	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	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Psychiatric Disorders	Mild	.	.	.
	Moderate	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary 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 44:
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	5	.	.
	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**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	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	.	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary 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	3	.	.
	Severe	.	.	.
Vascular Disorders	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 45:
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**	20	2	.
	Moderate	14	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	1	.
	Severe	.	.	.
General Disorders And Administration Site Conditions	**Mild**	2	.	.
	Moderate	.	.	.
	Severe	.	.	.
Immune System Disorders	**Mild**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	.	.	.
	Moderate	4	.	.
	Severe	1	.	.
Injury, Poisoning And Procedural Complications	Mild	3	.	.
	Moderate	3	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	1	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	1	.	.
	Moderate	.	1	.
	Severe	1	.	.
Musculoskeletal And Connective Tissue Disorders	Mild	2	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	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	3	.	.
	Severe	.	.	.
Vascular Disorders	Mild	4	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 46:
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	16	11	.
	Moderate	3	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	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	.	.	.
	Severe	.	.	.
Musculoskeletal And Connective Tissue Disorders	Mild	2	.	.
	Moderate	3	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary 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	2	2	.
	Moderate	.	.	.
	Severe	.	.	.
Vascular Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 47:
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	8	.	.
	Moderate	3	.	.
	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	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	.	.	.
	Moderate	1	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	Mild	3	.	.
	Moderate	.	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	.	.	.
	Moderate	.	.	.
	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	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Psychiatric Disorders	Mild	.	.	.
	Moderate	1	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Reproductive System And Breast Disorders	Mild	.	.	.
	Moderate	1	.	.
	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 48:
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**	23	3	.
	Moderate	1	.	.
	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**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	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	1	.	.
	Moderate	.	.	.
	Severe	.	.	.
Musculoskeletal And Connective Tissue Disorders	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	Mild	2	.	.
	Moderate	.	.	.
	Severe	.	.	.
Nervous System Disorders	Mild	.	1	.
	Moderate	.	.	.
	Severe	.	.	.
Psychiatric Disorders	Mild	.	.	.
	Moderate	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	1	.	.
	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 49:
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**	47	14	.
	Moderate	7	.	.
	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**	.	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Moderate	.	.	.
	Severe	.	.	.
Infections And Infestations	Mild	2	.	.
	Moderate	1	.	.
	Severe	.	.	.
Injury, Poisoning And Procedural Complications	Mild	18	.	.
	Moderate	.	.	.
	Severe	.	.	.
Investigations	Mild	.	.	.
	Moderate	.	.	.
	Severe	.	.	.
Metabolism And Nutrition Disorders	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.
Musculoskeletal And Connective Tissue Disorders	Mild	4	.	.
	Moderate	3	.	.
	Severe	.	.	.
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	Mild	2	.	.
	Moderate	.	.	.
	Severe	.	.	.
Nervous System Disorders	Mild	1	3	.
	Moderate	.	.	.
	Severe	.	.	.
Psychiatric Disorders	Mild	.	3	.
	Moderate	1	.	.

		Relationship to Vaccination		
MedDRA System Organ Class	Severity	Not Related (n)	Related (n)	Not Yet Determined (n)
	Severe	.	.	.
Renal And Urinary Disorders	Mild	.	.	.
	Moderate	1	.	.
	Severe	.	.	.
Reproductive System And Breast Disorders	Mild	.	.	.
	Moderate	1	.	.
	Severe	.	.	.
Respiratory, Thoracic And Mediastinal Disorders	Mild	1	.	.
	Moderate	.	.	.
	Severe	.	.	.
Skin And Subcutaneous Tissue Disorders	Mild	6	3	.
	Moderate	.	.	.
	Severe	.	.	.
Vascular Disorders	Mild	3	.	.
	Moderate	.	.	.
	Severe	.	.	.

TABLE 50:
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	34	30	4	.	29	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	9	8	1	.	9	.	.
	Contusion	3	3	.	.	3	.	.
	Limb injury	1	.	1	.	1	.	.
	Muscle strain	2	2	.	.	2	.	.
	Skin abrasion	1	1	.	.	1	.	.
	Skin laceration	1	1	.	.	1	.	.
	Wound	1	1	.	.	1	.	.
Metabolism and nutrition disorders	Iron deficiency	1	1	.	.	1	.	.
	Any PT	2	2	.	.	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)
Musculoskeletal and connective tissue disorders	**Muscular weakness**	1	1	.	.	.	1	.
	Pain in jaw	1	1	.	.	1	.	.
Nervous system disorders	**Presyncope**	1	1	.	.	1	.	.
Respiratory, thoracic and mediastinal disorders	**Any PT**	3	3	.	.	2	1	.
	Dyspnoea exertional	1	1	.	.	1	.	.
	Oropharyngeal pain	2	2	.	.	1	1	.
Skin and subcutaneous tissue disorders	**Any PT**	5	5	.	.	3	2	.
	Dermatitis contact	1	1	.	.	1	.	.
	Erythema	1	1	.	.	1	.	.
	Petechiae	1	1	.	.	.	1	.
	Photosensitivity reaction	1	1	.	.	1	.	.
	Urticaria	1	1	.	.	.	1	.
Vascular disorders	**Systolic hypertension**	1	1	.	.	1	.	.

TABLE 51:
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	30	22	8	.	23	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	5	1	4	.	4	1	.
	Abdominal pain	1	.	1	.	1	.	.
	Diarrhoea	1	.	1	.	.	1	.
	Dyspepsia	1	1	.	.	1	.	.
	Inguinal hernia	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	Any PT	2	1	1	.	2	.	.
	Respiratory tract infection	1	.	1	.	1	.	.
	Upper respiratory tract infection	1	1	.	.	1	.	.
	Any PT	3	3	.	.	3	.	.

			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)
Injury, poisoning and procedural complications	**Contusion**	1	1	.	.	1	.	.
	Skin abrasion	2	2	.	.	2	.	.
Investigations	**Blood glucose decreased**	1	1	.	.	1	.	.
Musculoskeletal and connective tissue disorders	**Any PT**	4	2	2	.	3	1	.
	Arthralgia	1	.	1	.	1	.	.
	Muscle spasms	1	1	.	.	.	1	.
	Myalgia	1	1	.	.	1	.	.
	Pain in extremity	1	.	1	.	1	.	.
Reproductive system and breast disorders	**Dysfunctional uterine bleeding**	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 52:
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	29	22	7	.	19	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	.	.

			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)
Nervous system disorders	**Dizziness**	1	1	.	.	1	.	.
Psychiatric disorders	**Any PT**	2	.	2	.	2	.	.
	Anxiety	1	.	1	.	1	.	.
	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 53:
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	45	25	17	3	27	18	.
Cardiac disorders	Bradycardia	2	2	.	.	2	.	.
Eye disorders	Scintillating scotoma	1	1	.	.	.	1	.
Gastrointestinal disorders	Any PT	8	6	1	1	6	2	.
	Abdominal pain upper	1	1	.	.	.	1	.
	Anal fissure	1	1	.	.	1	.	.
	Dyspepsia	1	1	.	.	1	.	.
	Gastritis	1	1	.	.	1	.	.
	Lip disorder	1	1	.	.	1	.	.
	Pancreatitis	1	.	1	.	1	.	.
	Parotid duct obstruction	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	3	2	1	.	3	.	.
	Bacterial vaginosis	1	1	.	.	1	.	.
	Epididymitis	1	.	1	.	1	.	.
	Urinary tract infection	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)
Injury, poisoning and procedural complications	**Skin injury**	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	.	.
	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**	3	2	1	.	2	1	.
	Anxiety	1	1	.	.	.	1	.
	Bipolar II disorder	1	.	1	.	1	.	.
	Insomnia	1	1	.	.	1	.	.
Reproductive system and breast disorders	**Any PT**	3	2	1	.	2	1	.
	Vaginal haemorrhage	1	1	.	.	.	1	.
	Vulvovaginal pruritus	2	1	1	.	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	.

			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)
Vascular disorders	**Any PT**	2	2	.	.	2	.	.
	Hypertension	1	1	.	.	1	.	.
	Hypotension	1	1	.	.	1	.	.

TABLE 54:
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	138	99	36	3	98	40	.
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	20	11	8	1	15	5	.
	Abdominal discomfort	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	.	.
	Gastritis	1	1	.	.	1	.	.
	Inguinal hernia	1	.	1	.	1	.	.
	Lip disorder	1	1	.	.	1	.	.
	Pancreatitis	1	.	1	.	1	.	.
	Parotid duct obstruction	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)
	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	.
	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	9	4	5	.	9	.	.
	Bacterial vaginosis	1	1	.	.	1	.	.
	Epididymitis	1	.	1	.	1	.	.
	Gastroenteritis	1	.	1	.	1	.	.
	Hordeolum	1	.	1	.	1	.	.
	Infected cyst	1	.	1	.	1	.	.
	Pustule	1	1	.	.	1	.	.
	Respiratory tract infection	1	.	1	.	1	.	.
	Upper respiratory tract infection	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)
	Urinary tract infection	1	1	.	.	1	.	.
Injury, poisoning and procedural complications	Any PT	16	13	3	.	16	.	.
	Contusion	4	4	.	.	4	.	.
	Limb injury	1	.	1	.	1	.	.
	Muscle strain	4	3	1	.	4	.	.
	Skin abrasion	3	3	.	.	3	.	.
	Skin injury	1	.	1	.	1	.	.
	Skin laceration	1	1	.	.	1	.	.
	Thermal burn	1	1	.	.	1	.	.
	Wound	1	1	.	.	1	.	.
Investigations	Any PT	2	2	.	.	2	.	.
	Blood glucose decreased	1	1	.	.	1	.	.
	Heart rate increased	1	1	.	.	1	.	.
Metabolism and nutrition disorders	Any PT	7	4	3	.	2	5	.
	Decreased appetite	5	3	2	.	.	5	.
	Hypoglycaemia	1	.	1	.	1	.	.
	Iron deficiency	1	1	.	.	1	.	.
Musculoskeletal and connective tissue disorders	Any PT	11	7	4	.	7	4	.
	Arthralgia	2	1	1	.	2	.	.
	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	2	1	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)
	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	5	2	3	.	4	1	.
	Anxiety	2	1	1	.	1	1	.
	Attention deficit hyperactivity disorder	1	.	1	.	1	.	.
	Bipolar II disorder	1	.	1	.	1	.	.
	Insomnia	1	1	.	.	1	.	.
Reproductive system and breast disorders	Any PT	5	4	1	.	4	1	.
	Breast pain	1	1	.	.	1	.	.
	Dysfunctional uterine bleeding	1	1	.	.	1	.	.
	Vaginal haemorrhage	1	1	.	.	.	1	.
	Vulvovaginal pruritus	2	1	1	.	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	.
	Any PT	8	6	2	.	4	4	.

			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)
Skin and subcutaneous tissue disorders	**Dermatitis contact**	1	1	.	.	1	.	.
	Erythema	1	1	.	.	1	.	.
	Hyperhidrosis	1	.	1	.	.	1	.
	Night sweats	1	.	1	.	.	1	.
	Petechiae	1	1	.	.	.	1	.
	Photosensitivity reaction	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 55:
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	17	11	6	.	15	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	Any PT	2	1	1	.	1	1	.
	Decreased appetite	1	.	1	.	.	1	.
	Glucose tolerance impaired	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	.	.
Vascular disorders	Any PT	3	3	.	.	3	.	.
	Diastolic hypertension	1	1	.	.	1	.	.
	Systolic hypertension	2	2	.	.	2	.	.

TABLE 56:
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**	11	5	5	1	10	1	.
Cardiac disorders	**Bradycardia**	2	2	.	.	2	.	.
Gastrointestinal disorders	**Any PT**	2	.	2	.	1	1	.
	Abdominal discomfort	1	.	1	.	.	1	.
	Gastrooesophageal reflux disease	1	.	1	.	1	.	.
Infections and infestations	**Any PT**	3	.	2	1	3	.	.
	Urinary tract infection	1	.	1	.	1	.	.
	Viral infection	2	.	1	1	2	.	.
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	.	.
Musculoskeletal and connective tissue disorders	**Osteoporosis**	1	1	.	.	1	.	.

TABLE 57:
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	12	6	5	1	11	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	3	.	3	.	3	.	.
	Dermatitis contact	2	.	2	.	2	.	.
	Rash maculo-papular	1	.	1	.	1	.	.
Vascular disorders	Systolic hypertension	1	1	.	.	1	.	.

TABLE 58:
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	40	22	16	2	36	4	.
Cardiac disorders	Bradycardia	2	2	.	.	2	.	.
Ear and labyrinth disorders	Vertigo	1	1	.	.	.	1	.
Gastrointestinal disorders	Any PT	3	1	2	.	2	1	.
	Abdominal discomfort	1	.	1	.	.	1	.
	Gastrooesophageal reflux disease	1	.	1	.	1	.	.
	Haemorrhoids	1	1	.	.	1	.	.
General disorders and administration site conditions	Injection site bruising	2	2	.	.	2	.	.
Infections and infestations	Any PT	5	.	4	1	5	.	.
	Onychomycosis	1	.	1	.	1	.	.
	Paronychia	1	.	1	.	1	.	.
	Urinary tract infection	1	.	1	.	1	.	.
	Viral infection	2	.	1	1	2	.	.
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	.	.

			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	**Bone density decreased**	1	.	1	.	1	.	.
Metabolism and nutrition disorders	**Any PT**	3	1	1	1	2	1	.
	Decreased appetite	1	.	1	.	.	1	.
	Glucose tolerance impaired	1	1	.	.	1	.	.
	Hypoglycaemia	1	.	.	1	1	.	.
Musculoskeletal and connective tissue disorders	**Any PT**	2	2	.	.	2	.	.
	Osteoporosis	1	1	.	.	1	.	.
	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**	3	.	3	.	3	.	.
	Dermatitis contact	2	.	2	.	2	.	.
	Rash maculo-papular	1	.	1	.	1	.	.
Vascular disorders	**Any PT**	4	4	.	.	4	.	.
	Diastolic hypertension	1	1	.	.	1	.	.
	Systolic hypertension	3	3	.	.	3	.	.

TABLE 59:
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	30	27	3	.	19	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	5	2	3	.	5	.	.
	Arthritis	1	.	1	.	1	.	.
	Joint swelling	1	1	.	.	1	.	.
	Medial tibial stress syndrome	1	.	1	.	1	.	.
	Muscle tightness	1	1	.	.	1	.	.
	Musculoskeletal chest pain	1	.	1	.	1	.	.
Nervous system disorders	Any PT	3	3	.	.	1	2	.

			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)
	Dizziness	2	2	.	.	1	1	.
	Visual field defect	1	1	.	.	.	1	.
Psychiatric disorders	**Any PT**	3	3	.	.	.	3	.
	Anxiety	1	1	.	.	.	1	.
	Sleep disorder	2	2	.	.	.	2	.
Skin and subcutaneous tissue disorders	**Any PT**	4	4	.	.	2	2	.
	Actinic keratosis	1	1	.	.	1	.	.
	Night sweats	1	1	.	.	.	1	.
	Pruritus	1	1	.	.	.	1	.
	Skin irritation	1	1	.	.	1	.	.

TABLE 60:
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	11	8	3	.	11	.	.
General disorders and administration site conditions	Injection site bruising	1	1	.	.	1	.	.
Infections and infestations	Cellulitis	1	.	1	.	1	.	.
Injury, poisoning and procedural complications	Any PT	3	3	.	.	3	.	.
	Arthropod bite	1	1	.	.	1	.	.
	Injury	2	2	.	.	2	.	.
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	.	.	1	.	.
Psychiatric disorders	Depression	1	.	1	.	1	.	.
Reproductive system and breast disorders	Benign prostatic hyperplasia	1	.	1	.	1	.	.
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	1	1	.	.	1	.	.
Vascular disorders	Hypertension	2	2	.	.	2	.	.

TABLE 61:
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	27	26	1	.	24	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	.	.
Metabolism and nutrition disorders	Hypercholesterolaemia	1	1	.	.	1	.	.
Musculoskeletal and connective tissue disorders	Myalgia	1	1	.	.	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Any PT	2	2	.	.	2	.	.
	Malignant melanoma	1	1	.	.	1	.	.
	Squamous cell carcinoma	1	1	.	.	1	.	.
Nervous system disorders	Dizziness	1	1	.	.	.	1	.
Renal and urinary disorders	Renal mass	1	.	1	.	1	.	.
Skin and subcutaneous tissue disorders	Any PT	5	5	.	.	4	1	.
	Blister	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)
	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 62:
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	68	61	7	.	54	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	3	2	1	.	3	.	.
	Cellulitis	1	.	1	.	1	.	.
	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	.	.

			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)
	Tooth fracture	1	1	.	.	1	.	.
Metabolism and nutrition disorders	Hypercholesterolaemia	1	1	.	.	1	.	.
Musculoskeletal and connective tissue disorders	Any PT	7	4	3	.	7	.	.
	Arthritis	1	.	1	.	1	.	.
	Joint swelling	1	1	.	.	1	.	.
	Medial tibial stress syndrome	1	.	1	.	1	.	.
	Muscle tightness	1	1	.	.	1	.	.
	Musculoskeletal chest pain	1	.	1	.	1	.	.
	Myalgia	1	1	.	.	1	.	.
	Osteoarthritis	1	1	.	.	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Any PT	2	2	.	.	2	.	.
	Malignant melanoma	1	1	.	.	1	.	.
	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	4	3	1	.	1	3	.
	Anxiety	1	1	.	.	.	1	.
	Depression	1	.	1	.	1	.	.
	Sleep disorder	2	2	.	.	.	2	.
Renal and urinary disorders	Renal mass	1	.	1	.	1	.	.
Reproductive system and breast disorders	Benign prostatic hyperplasia	1	.	1	.	1	.	.
Respiratory, thoracic and mediastinal disorders	Oropharyngeal 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)
Skin and subcutaneous tissue disorders	**Any PT**	9	9	.	.	6	3	.
	Actinic keratosis	1	1	.	.	1	.	.
	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 63:
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	4	27	-	-	12	80	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	6	40	5	33	1	7	-	-	6	40	-	-
	Contusion	3	20	3	20	-	-	-	-	3	20	-	-
	Limb injury	1	7	-	-	1	7	-	-	1	7	-	-
	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	-	-
Metabolism and nutrition disorders	Iron deficiency	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

				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	%
	Pain in jaw	1	7	1	7	-	-	-	-	1	7	-	-
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	-	-	-	-	3	20	2	13
	Dermatitis contact	1	7	1	7	-	-	-	-	1	7	-	-
	Erythema	1	7	1	7	-	-	-	-	1	7	-	-
	Petechiae	1	7	1	7	-	-	-	-	-	-	1	7
	Photosensitivity reaction	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 64:
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	11	73	10	67	4	27	-	-	9	60	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	4	27	1	7	3	20	-	-	4	27	1	7
	Abdominal pain	1	7	-	-	1	7	-	-	1	7	-	-
	Diarrhoea	1	7	-	-	1	7	-	-	-	-	1	7
	Dyspepsia	1	7	1	7	-	-	-	-	1	7	-	-
	Inguinal hernia	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	Any PT	2	13	1	7	1	7	-	-	2	13	-	-
	Respiratory tract infection	1	7	-	-	1	7	-	-	1	7	-	-
	Upper respiratory tract infection	1	7	1	7	-	-	-	-	1	7	-	-
	Any PT	3	20	3	20	-	-	-	-	3	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**	**%**
Injury, poisoning and procedural complications	**Contusion**	1	7	1	7	-	-	-	-	1	7	-	-
	Skin abrasion	2	13	2	13	-	-	-	-	2	13	-	-
Investigations	**Blood glucose decreased**	1	7	1	7	-	-	-	-	1	7	-	-
Musculoskeletal and connective tissue disorders	**Any PT**	3	20	2	13	1	7	-	-	2	13	1	7
	Arthralgia	1	7	-	-	1	7	-	-	1	7	-	-
	Muscle spasms	1	7	1	7	-	-	-	-	-	-	1	7
	Myalgia	1	7	1	7	-	-	-	-	1	7	-	-
	Pain in extremity	1	7	-	-	1	7	-	-	1	7	-	-
Reproductive system and breast disorders	**Dysfunctional uterine bleeding**	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 65:
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	12	80	9	60	6	40	-	-	10	67	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	-	-
Nervous system disorders	Dizziness	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	%
Psychiatric disorders	**Any PT**	2	13	-	-	2	13	-	-	2	13	-	-
	Anxiety	1	7	-	-	1	7	-	-	1	7	-	-
	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 66:
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	12	80	7	47	10	67	2	13	10	67	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	7	47	5	33	1	7	1	7	5	33	2	13
	Abdominal pain upper	1	7	1	7	-	-	-	-	-	-	1	7
	Anal fissure	1	7	1	7	-	-	-	-	1	7	-	-
	Dyspepsia	1	7	1	7	-	-	-	-	1	7	-	-
	Gastritis	1	7	1	7	-	-	-	-	1	7	-	-
	Lip disorder	1	7	1	7	-	-	-	-	1	7	-	-
	Pancreatitis	1	7	-	-	1	7	-	-	1	7	-	-
	Parotid duct obstruction	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	-	-
	Bacterial vaginosis	1	7	1	7	-	-	-	-	1	7	-	-
	Epididymitis	1	7	-	-	1	7	-	-	1	7	-	-
	Urinary tract infection	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	%
Injury, poisoning and procedural complications	Skin injury	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	-	-
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	2	13	1	7	1	7	-	-	2	13	1	7
	Anxiety	1	7	1	7	-	-	-	-	-	-	1	7
	Bipolar II disorder	1	7	-	-	1	7	-	-	1	7	-	-
	Insomnia	1	7	1	7	-	-	-	-	1	7	-	-
Reproductive system and breast disorders	Any PT	3	20	2	13	1	7	-	-	2	13	1	7
	Vaginal haemorrhage	1	7	1	7	-	-	-	-	-	-	1	7
	Vulvovaginal pruritus	2	13	1	7	1	7	-	-	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

				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**	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 67:
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	47	78	38	63	24	40	2	3	41	68	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	17	28	9	15	7	12	1	2	13	22	5	8
	Abdominal discomfort	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	-	-
	Gastritis	1	2	1	2	-	-	-	-	1	2	-	-
	Inguinal hernia	1	2	-	-	1	2	-	-	1	2	-	-
	Lip disorder	1	2	1	2	-	-	-	-	1	2	-	-
	Pancreatitis	1	2	-	-	1	2	-	-	1	2	-	-
	Parotid duct obstruction	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	%
	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	-	-
	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	8	13	3	5	5	8	-	-	8	13	-	-
	Bacterial vaginosis	1	2	1	2	-	-	-	-	1	2	-	-
	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	-	-
	Respiratory tract infection	1	2	-	-	1	2	-	-	1	2	-	-
	Upper respiratory tract infection	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	%
	Urinary tract infection	1	2	1	2	-	-	-	-	1	2	-	-
Injury, poisoning and procedural complications	Any PT	13	22	10	17	3	5	-	-	13	22	-	-
	Contusion	4	7	4	7	-	-	-	-	4	7	-	-
	Limb injury	1	2	-	-	1	2	-	-	1	2	-	-
	Muscle strain	4	7	3	5	1	2	-	-	4	7	-	-
	Skin abrasion	3	5	3	5	-	-	-	-	3	5	-	-
	Skin injury	1	2	-	-	1	2	-	-	1	2	-	-
	Skin laceration	1	2	1	2	-	-	-	-	1	2	-	-
	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	6	10	3	5	3	5	-	-	2	3	4	7
	Decreased appetite	4	7	2	3	2	3	-	-	-	-	4	7
	Hypoglycaemia	1	2	-	-	1	2	-	-	1	2	-	-
	Iron deficiency	1	2	1	2	-	-	-	-	1	2	-	-
Musculoskeletal and connective tissue disorders	Any PT	10	17	7	12	3	5	-	-	6	10	4	7
	Arthralgia	2	3	1	2	1	2	-	-	2	3	-	-
	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	2	3	1	2	1	2	-	-	1	2	1	2
	Pain in jaw	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	%
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	4	7	1	2	3	5	-	-	4	7	1	2
	Anxiety	2	3	1	2	1	2	-	-	1	2	1	2
	Attention deficit hyperactivity disorder	1	2	-	-	1	2	-	-	1	2	-	-
	Bipolar II disorder	1	2	-	-	1	2	-	-	1	2	-	-
	Insomnia	1	2	1	2	-	-	-	-	1	2	-	-
Reproductive system and breast disorders	Any PT	5	8	4	7	1	2	-	-	4	7	1	2
	Breast pain	1	2	1	2	-	-	-	-	1	2	-	-
	Dysfunctional uterine bleeding	1	2	1	2	-	-	-	-	1	2	-	-
	Vaginal haemorrhage	1	2	1	2	-	-	-	-	-	-	1	2
	Vulvovaginal pruritus	2	3	1	2	1	2	-	-	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	-	-	4	7	4	7
	Dermatitis contact	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	%
	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
	Photosensitivity reaction	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 68:
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	8	80	7	70	4	40	-	-	6	60	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	Any PT	2	20	1	10	1	10	-	-	1	10	1	10
	Decreased appetite	1	10	-	-	1	10	-	-	-	-	1	10
	Glucose tolerance impaired	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	-	-
Vascular disorders	Any PT	1	10	1	10	-	-	-	-	1	10	-	-
	Diastolic hypertension	1	10	1	10	-	-	-	-	1	10	-	-
	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 69:
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	5	50	5	50	1	10	7	70	1	10
Cardiac disorders	**Bradycardia**	2	20	2	20	-	-	-	-	2	20	-	-
Gastrointestinal disorders	**Any PT**	2	20	-	-	2	20	-	-	1	10	1	10
	Abdominal discomfort	1	10	-	-	1	10	-	-	-	-	1	10
	Gastrooesophageal reflux disease	1	10	-	-	1	10	-	-	1	10	-	-
Infections and infestations	**Any PT**	3	30	-	-	2	20	1	10	3	30	-	-
	Urinary tract infection	1	10	-	-	1	10	-	-	1	10	-	-
	Viral infection	2	20	-	-	1	10	1	10	2	20	-	-
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	-	-
Musculoskeletal and connective tissue disorders	**Osteoporosis**	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 70:
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 71:
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	23	77	17	57	11	37	2	7	21	70	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	3	10	1	3	2	7	-	-	2	7	1	3
	Abdominal discomfort	1	3	-	-	1	3	-	-	-	-	1	3
	Gastrooesophageal reflux disease	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	5	17	-	-	4	13	1	3	5	17	-	-
	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	2	7	-	-	1	3	1	3	2	7	-	-
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	-	-

				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	Any PT	3	10	1	3	1	3	1	3	2	7	1	3
	Decreased appetite	1	3	-	-	1	3	-	-	-	-	1	3
	Glucose tolerance impaired	1	3	1	3	-	-	-	-	1	3	-	-
	Hypoglycaemia	1	3	-	-	-	-	1	3	1	3	-	-
Musculoskeletal and connective tissue disorders	Any PT	2	7	2	7	-	-	-	-	2	7	-	-
	Osteoporosis	1	3	1	3	-	-	-	-	1	3	-	-
	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	Any PT	2	7	2	7	-	-	-	-	2	7	-	-
	Diastolic hypertension	1	3	1	3	-	-	-	-	1	3	-	-
	Systolic hypertension	2	7	2	7	-	-	-	-	2	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 72:
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	-	-
	Medial tibial stress syndrome	1	10	-	-	1	10	-	-	1	10	-	-
	Muscle tightness	1	10	1	10	-	-	-	-	1	10	-	-
	Musculoskeletal chest pain	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**	**%**
Nervous system disorders	**Any PT**	2	20	2	20	-	-	-	-	1	10	2	20
	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
	Actinic keratosis	1	10	1	10	-	-	-	-	1	10	-	-
	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 73:
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	7	70	7	70	2	20	-	-	7	70	-	-
General disorders and administration site conditions	Injection site bruising	1	10	1	10	-	-	-	-	1	10	-	-
Infections and infestations	Cellulitis	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	-	-
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	10	1	10	-	-	-	-	1	10	-	-
Psychiatric disorders	Depression	1	10	-	-	1	10	-	-	1	10	-	-
Reproductive system and breast disorders	Benign prostatic hyperplasia	1	10	-	-	1	10	-	-	1	10	-	-
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 74:
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	9	90	8	80	1	10	-	-	8	80	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	-	-
Metabolism and nutrition disorders	Hypercholesterolaemia	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)	Any PT	1	10	1	10	-	-	-	-	1	10	-	-
	Malignant melanoma	1	10	1	10	-	-	-	-	1	10	-	-
	Squamous cell carcinoma	1	10	1	10	-	-	-	-	1	10	-	-
Nervous system disorders	Dizziness	1	10	1	10	-	-	-	-	-	-	1	10
Renal and urinary disorders	Renal mass	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	-	-

				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**	**%**
	Dermatitis contact	1	10	1	10	-	-	-	-	1	10	-	-
	Night sweats	1	10	1	10	-	-	-	-	-	-	1	10
	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 75:
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	25	83	24	80	5	17	-	-	22	73	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	3	10	2	7	1	3	-	-	3	10	-	-
	Cellulitis	1	3	-	-	1	3	-	-	1	3	-	-
	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	-	-
Metabolism and nutrition disorders	Hypercholesterolaemia	1	3	1	3	-	-	-	-	1	3	-	-
Musculoskeletal and connective tissue disorders	Any PT	6	20	4	13	2	7	-	-	6	20	-	-
	Arthritis	1	3	-	-	1	3	-	-	1	3	-	-
	Joint swelling	1	3	1	3	-	-	-	-	1	3	-	-
	Medial tibial stress syndrome	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	-	-
	Osteoarthritis	1	3	1	3	-	-	-	-	1	3	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Any PT	1	3	1	3	-	-	-	-	1	3	-	-
	Malignant melanoma	1	3	1	3	-	-	-	-	1	3	-	-
	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	3	10	2	7	1	3	-	-	1	3	2	7
	Anxiety	1	3	1	3	-	-	-	-	-	-	1	3
	Depression	1	3	-	-	1	3	-	-	1	3	-	-
	Sleep disorder	1	3	1	3	-	-	-	-	-	-	1	3
Renal and urinary disorders	Renal mass	1	3	-	-	1	3	-	-	1	3	-	-
Reproductive system and breast disorders	Benign prostatic hyperplasia	1	3	-	-	1	3	-	-	1	3	-	-
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	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	%
Skin and subcutaneous tissue disorders	**Any PT**	7	23	7	23	-	-	-	-	4	13	3	10
	Actinic keratosis	1	3	1	3	-	-	-	-	1	3	-	-
	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	-	-
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.

Table 76: Overall Summary of Adverse Events by Vaccination 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	11	73	12	80	12	80	47	78
	.	.	.	.	.	.	.	.	.	.
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	2	13	2	3
Related	0	0	0	0	0	0	1	7	1	2
Unrelated	0	0	0	0	0	0	1	7	1	2
	.	.	.	.	.	.	.	.	.	.
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	7	47	4	27	3	20	7	47	21	35

	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	1	7	1	7	2	3
At least one related medically attended adverse event	0	0	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	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 X.
[c]As reported on the Adverse Event eCRF.

Table 77: Overall Summary of Adverse Events by Vaccination 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	8	80	7	70	8	80	23	77
	.	.	.	.	.	.	.	.
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	6	60	1	10	9	30

	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	2	20	0	0	3	10
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 X.
[c]As reported on the Adverse Event eCRF.

Table 78: Overall Summary of Adverse Events by Vaccination 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	7	70	9	90	25	83
	.	.	.	.	.	.	.	.
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	1	10	1	3
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	2	20	3	30	5	50	10	33

	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	1	10	1	10	2	7
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 X.
[c]As reported on the Adverse Event eCRF.

Figure 43: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity 18-55 Years of Age

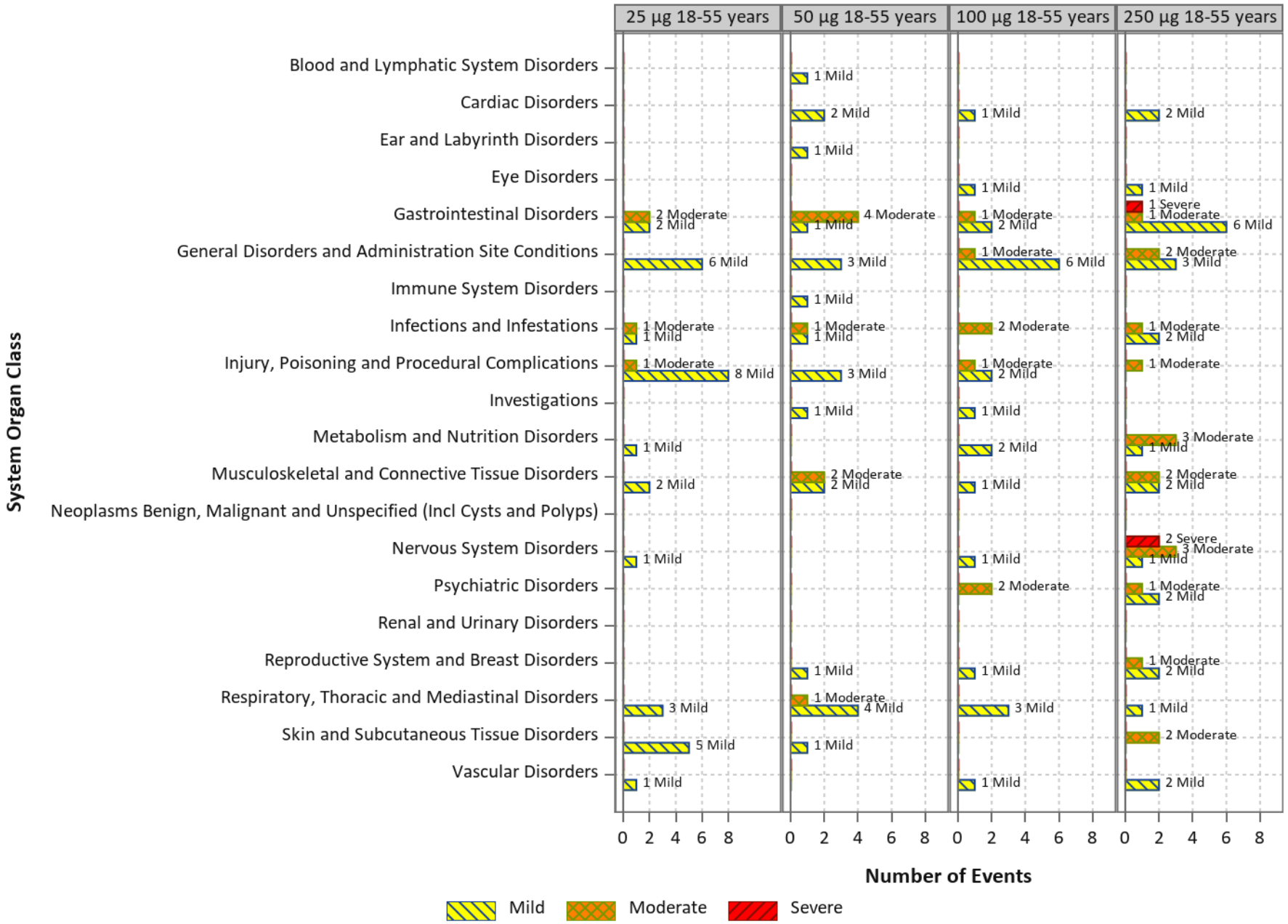

Figure 44: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity 56-70 Years of Age

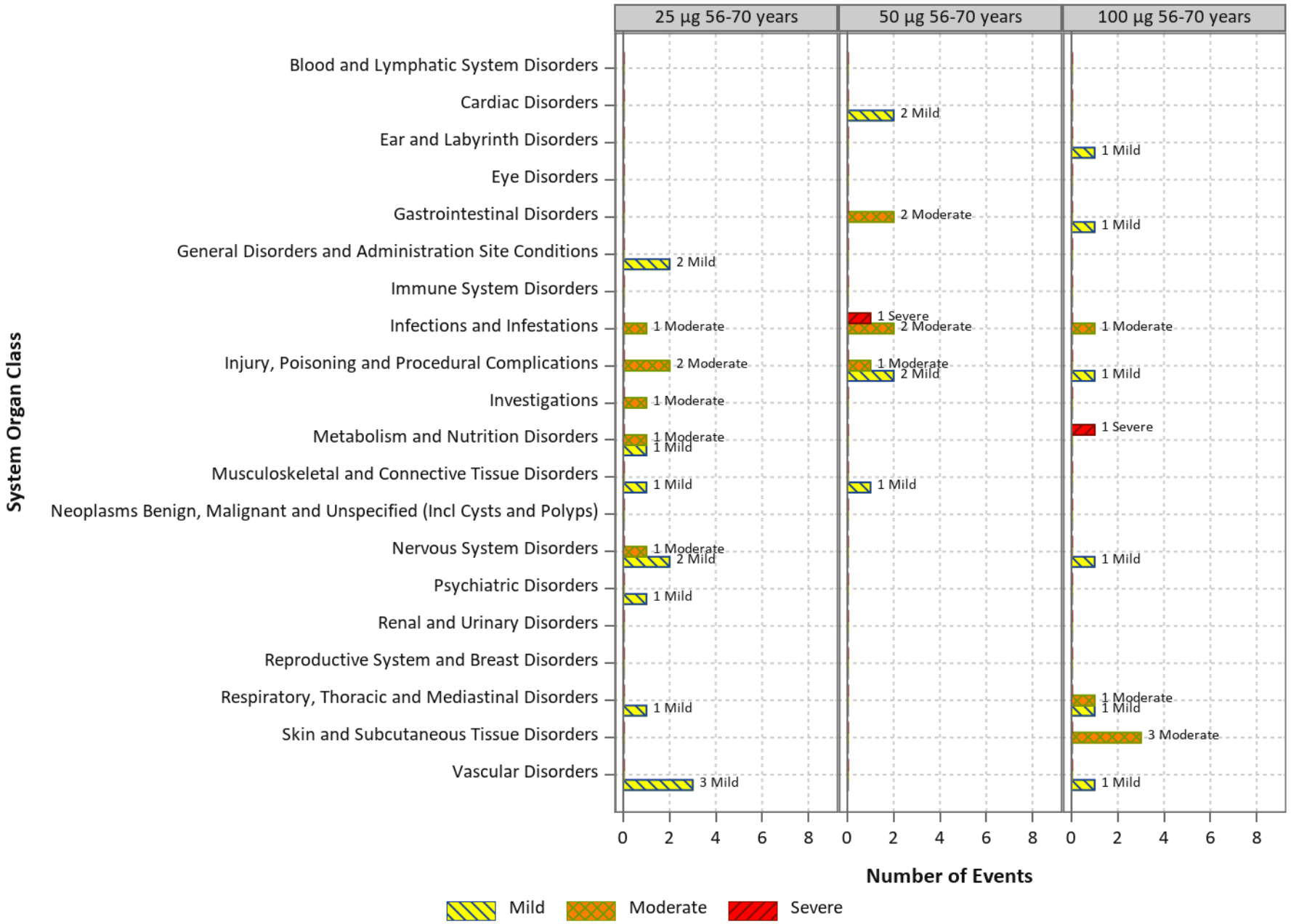

Figure 45: Frequency of Related Adverse Events by MedDRA System Organ Class and Severity ≥71 years of Age

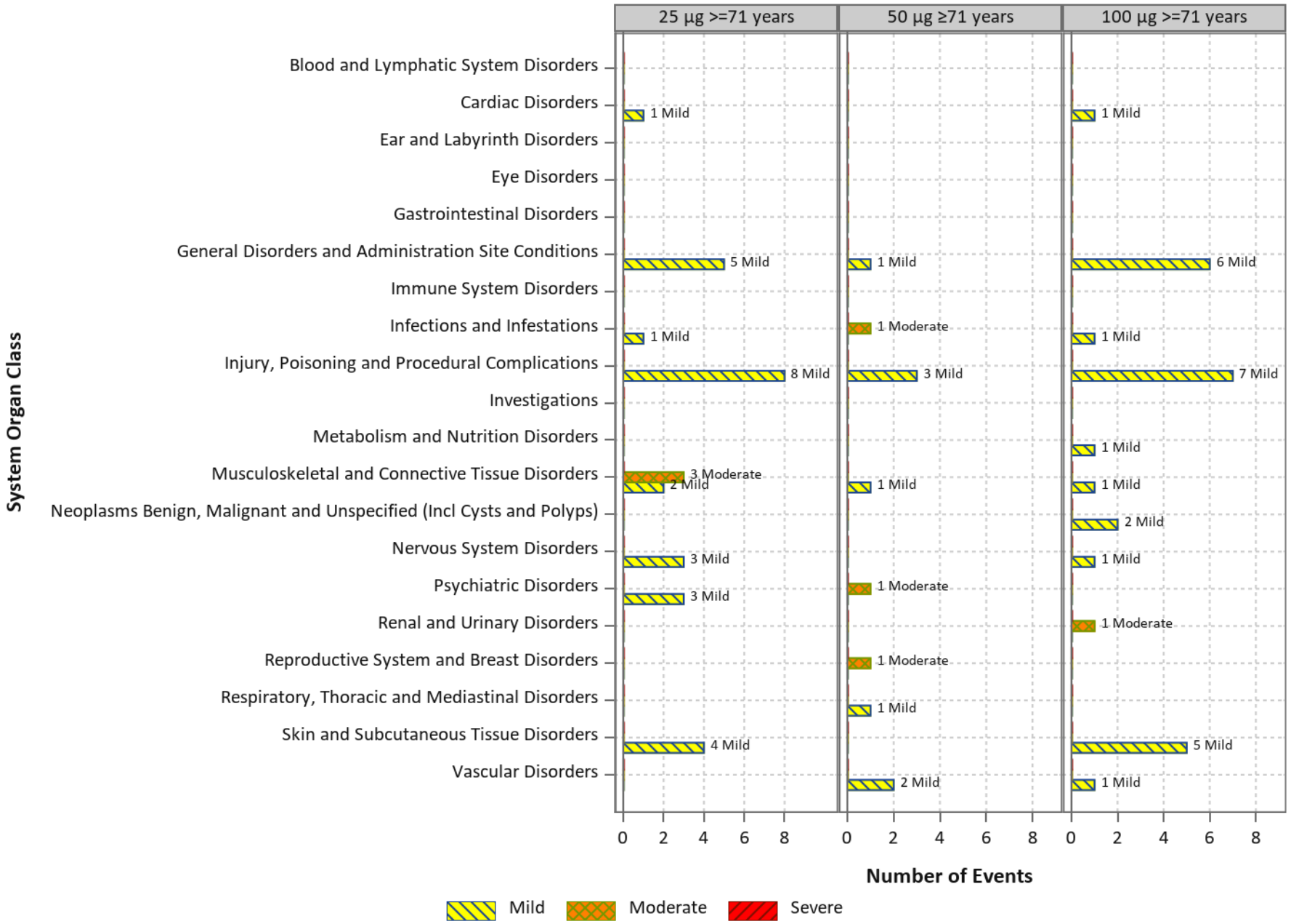

TABLE 79:
Listing of New Serious Adverse Events

Adverse Event	Associated with Dose No.	No. of Days Post Associated Vaccination (Duration)	Duration of SAE (days)	Reason Reported as an SAE	Severity	Relationship to Vaccination	If Not Related, Alternative Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to AE	Outcome	MedDRA® Sytem Organ Class	MedDRA® Preferred Term
Vaccination Group: 100 µg (≥71 years), Subject ID: COV.00176												
RENAL MASS	02	170 (22)	1	Hospitalization /Prolonged Hospitalization	Moderate	Not related	Other medical condition or illness: abnormal cell division	NA- Not applicable	No	Recovered /resolved	Renal and urinary disorders	Renal mass
Comments:												

Table 80: Listing of New Adverse Events

Subject ID	Vaccination Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	No. of Days Post Associated Vaccination (Duration)	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00092	250 µg (18-55 years)	Acute Gastritis	02	11MAY2020	122 (61)	10SEP2020	Gastrointestinal disorders	Yes	No	Not related	Recovered /resolved
COV.00111	25 µg (56-70 years)	Worsening of Prediabetes	02	18MAY2020	89 (Ongoing)	15AUG2020	Metabolism and nutrition disorders	Yes	No	Not related	Not recovered/ Not resolved
COV.00138	100 µg (56-70 years)	Contact Dermatitis	01	23APR2020	150 (14)	20SEP2020	Skin and subcutaneous tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00215	50 µg (18-55 years)	Inguinal Hernia	02	01JUL2020	93 (Ongoing)	02OCT2020	Gastrointestinal disorders	Yes	No	Not related	Not recovered/ Not resolved
COV.00215	50 µg (18-55 years)	Shoulder Pain	02	01JUL2020	106 (Ongoing)	15OCT2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovering /resolving
COV.00215	50 µg (18-55 years)	Heel Pain	02	01JUL2020	137 (Ongoing)	15NOV2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovering /resolving
COV.00234	50 µg (18-55 years)	Acute Respiratory Tract Infection	02	30JUN2020	179 (41)	26DEC2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00048	100 µg (18-55 years)	Anxiety	02	24APR2020	-9 (Ongoing)	15APR2020	Psychiatric disorders	Yes	Yes	Not related	Recovering /resolving
COV.00093	250 µg (18-55 years)	Parotid Duct Obstruction	02	12MAY2020	185 (Ongoing)	13NOV2020	Gastrointestinal disorders	Yes	No	Not related	Recovering /resolving
COV.00112	25 µg (56-70 years)	Diastolic Hypertension	01	20APR2020	28 (9)	18MAY2020	Vascular disorders			Not related	Recovered /resolved

Subject ID	Vaccination Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	No. of Days Post Associated Vaccination (Duration)	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00112	25 µg (56-70 years)	Systolic Hypertension	01	20APR2020	7 (8)	27APR2020	Vascular disorders			Not related	Recovered /resolved
COV.00112	25 µg (56-70 years)	Systolic Hypertension	02	18MAY2020	28 (Ongoing)	15JUN2020	Vascular disorders			Not related	Not recovered/ Not resolved
COV.00007	25 µg (18-55 years)	Iron Deficiency	02	14APR2020	167 (Ongoing)	28SEP2020	Metabolism and nutrition disorders	Yes	No	Not related	
COV.00024	25 µg (18-55 years)	Hand Trauma	02	21APR2020	178 (Ongoing)	16OCT2020	Injury, poisoning and procedural complications	Yes	No	Not related	Not recovered/ Not resolved
COV.00027	25 µg (18-55 years)	Photocontact Dermatitis	01	24MAR2020	145 (8)	16AUG2020	Skin and subcutaneous tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00079	250 µg (18-55 years)	Bacterial Vaginosis	01	08APR2020	167 (3)	22SEP2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00087	250 µg (18-55 years)	Avulsed Skin	02	11MAY2020	94 (49)	13AUG2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00085	250 µg (18-55 years)	Bipolar Ii Disorder	02	11MAY2020	84 (Ongoing)	03AUG2020	Psychiatric disorders	Yes	Yes	Not related	Not recovered/ Not resolved
COV.00160	25 µg (≥71 years)	Hypertrophic Actinic Keratosis	02	01JUN2020	167 (27)	15NOV2020	Skin and subcutaneous tissue disorders	Yes	No	Not related	Recovered /resolved

Subject ID	Vaccination Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	No. of Days Post Associated Vaccination (Duration)	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00167	25 µg (≥71 years)	Shin Splints	02	02JUN2020	150 (78)	30OCT2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovered /resolved
COV.00168	100 µg (≥71 years)	Hypercholesterolemia	02	02JUN2020	167 (Ongoing)	16NOV2020	Metabolism and nutrition disorders	Yes	Yes	Not related	Not recovered/ Not resolved
COV.00176	100 µg (≥71 years)	Renal Mass	02	08JUN2020	170 (22)	25NOV2020	Renal and urinary disorders	Yes	No	Not related	Recovered /resolved
COV.00177	100 µg (≥71 years)	Malignant Melanoma	02	08JUN2020	79 (28)	26AUG2020	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Yes	No	Not related	Recovered /resolved
COV.00254	50 µg (18-55 years)	Chest Wall Contusion	02	13JUL2020	141 (32)	01DEC2020	Injury, poisoning and procedural complications	Yes	No	Not related	Recovered /resolved
COV.00254	50 µg (18-55 years)	Dysfunctional Uterine Bleeding	02	13JUL2020	94 (Ongoing)	15OCT2020	Reproductive system and breast disorders	Yes	No	Not related	
COV.00240	50 µg (≥71 years)	Cellulitis	02	01JUL2020	92 (8)	01OCT2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00207	50 µg (56-70 years)	Viral Syndrome	02	02JUL2020	151 (3)	30NOV2020	Infections and infestations	Yes	No	Not related	Recovered /resolved
COV.00212	50 µg (56-70 years)	Osteoporosis	02	29JUN2020	78 (Ongoing)	15SEP2020	Musculoskeletal and connective tissue disorders	Yes	Yes	Not related	Recovering /resolving
COV.00216	50 µg (56-70 years)	Gastroesophageal Reflux	02	29JUN2020	155 (Ongoing)	01DEC2020	Gastrointestinal disorders	Yes	No	Not related	Recovering /resolving

Subject ID	Vaccination Group	Event Description	Number of Doses Received at Time of Event	Date of Product Administration[a]	No. of Days Post Associated Vaccination (Duration)	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome
COV.00241	50 µg (≥71 years)	Worsening Depression and Anxiety	02	01JUL2020	173 (8)	21DEC2020	Psychiatric disorders	Yes	No	Not related	Recovered /resolved
COV.00241	50 µg (≥71 years)	Benign Prostatic Hyperplasia	02	01JUL2020	90 (Ongoing)	29SEP2020	Reproductive system and breast disorders	Yes	Yes	Not related	Recovering /resolving
COV.00238	50 µg (≥71 years)	Osteoarthritis Exacerbation	02	01JUL2020	76 (8)	15SEP2020	Musculoskeletal and connective tissue disorders	Yes	No	Not related	Recovered /resolved

[a]Date of most recent dose/product administration.
[b]Related, Not Related.

Table 81: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	14	93	15	100	14	93	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Day 209	**None**	15	100	14	93	14	93	12	80	55	92
	Mild	-	-	-	-	1	7	3	20	4	7
	Moderate	-	-	1	7	-	-	-	-	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	13	87	11	73	13	87	10	67	47	78
	Mild	2	13	3	20	2	13	4	27	11	18
	Moderate	-	-	1	7	-	-	1	7	2	3
	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 82: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 209	**None**	15	100	15	100	15	100	15	100	60	100
	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 83: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 209	**None**	15	100	14	93	15	100	12	80	56	93
	Mild	-	-	1	7	-	-	3	20	4	7
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	15	100	14	93	15	100	12	80	56	93
	Mild	-	-	1	7	-	-	3	20	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 84: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	14	93	15	100	14	93	58	97
	Mild	-	-	1	7	-	-	-	-	1	2
	Moderate	-	-	-	-	-	-	1	7	1	2
	Severe	-	-	-	-	-	-	-	-	-	-
Day 209	**None**	15	100	14	93	14	93	15	100	58	97
	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	-	-	3	20	2	13	-	-	5	8
	Moderate	-	-	1	7	-	-	1	7	2	3
	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 85: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	15	100	15	100	15	100	60	100
	Mild	-	-	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-	-	-
Day 209	**None**	15	100	15	100	15	100	15	100	60	100
	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 86: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	8	80	9	90	10	100	27	90
	Mild	1	10	-	-	-	-	1	3
	Moderate	1	10	-	-	-	-	1	3
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	7	70	8	80	6	60	21	70
	Mild	1	10	2	20	3	30	6	20
	Moderate	2	20	-	-	1	10	3	10
	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 87: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 57	None	9	90	10	100	10	100	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**	8	80	10	100	9	90	27	90
	Mild	1	10	-	-	1	10	2	7
	Moderate	1	10	-	-	-	-	1	3
	Severe	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	9	90	10	100	28	93
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	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 88: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
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**	9	90	10	100	10	100	29	97
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	9	90	10	100	28	93
	Mild	-	-	-	-	-	-	-	-
	Moderate	1	10	-	-	-	-	1	3
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	9	90	10	100	9	90	28	93
	Mild	-	-	-	-	1	10	1	3
	Moderate	1	10	-	-	-	-	1	3
	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 89: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 57	None	10	100	10	100	10	100	30	100

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	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 119	**None**	10	100	10	100	10	100	30	100
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	9	90	10	100	28	93
	Mild	1	10	-	-	-	-	1	3
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	9	90	8	80	10	100	27	90
	Mild	1	10	2	20	-	-	3	10
	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 90: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	10	100	9	90	10	100	29	97
	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 91: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	8	80	7	70	9	90	24	80
	Mild	1	10	2	20	-	-	3	10
	Moderate	-	-	-	-	1	10	1	3
	Severe	-	-	1	10	-	-	1	3
Max Severity Post Baseline	**None**	7	70	7	70	6	60	20	67
	Mild	3	30	2	20	3	30	8	27
	Moderate	-	-	-	-	1	10	1	3
	Severe	-	-	1	10	-	-	1	3

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 92: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	9	90	10	100	28	93
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	1	10	-	-	1	3
Max Severity Post Baseline	**None**	8	80	9	90	7	70	24	80
	Mild	2	20	-	-	3	30	5	17
	Moderate	-	-	-	-	-	-	-	-
	Severe	-	-	1	10	-	-	1	3

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 93: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	10	100	9	90	28	93
	Mild	-	-	-	-	-	-	-	-
	Moderate	-	-	-	-	1	10	1	3
	Severe	-	-	-	-	-	-	-	-
Max Severity Post Baseline	**None**	10	100	9	90	9	90	28	93
	Mild	-	-	1	10	-	-	1	3
	Moderate	-	-	-	-	1	10	1	3
	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 94: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	8	80	8	80	10	100	26	87
	Mild	1	10	2	20	-	-	3	10
	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 95: Vital Signs by Assessment, Maximum Severity, Time Point, and Vaccination 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	-	-	-	-	-	-	-	-
Day 209	**None**	9	90	10	100	10	100	29	97
	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 were reported in the study by the data cutoff date of this CSR Addendum 1. Case narratives for participants who discontinued study vaccine administration through Day 119 for Cohorts 1 through 5, 7, and 8 and through Day 57 for Cohorts 10 through 12 due to an AE are provided in the Day 119 CSR (Section 7.3.3.1). No participant discontinued the study due to an AE between data cutoff date of Day 119 CSR and data cutoff date of this CSR Addendum 1.

One participant reported in an SAE in during the study. The case narrative for this participant is provided in Section 7.3.2.

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)