CLINICAL RESEARCH IN INFECTIOUS DISEASES

STATISTICAL ANALYSIS PLAN
FOR
DMID PROTOCOL: 21-0002 (COHORT 2)

STUDY TITLE:

PHASE I, OPEN-LABEL, RANDOMIZED STUDY OF THE SAFETY AND IMMUNOGENICITY OF A SARS-CoV-2 VARIANT VACCINE (mRNA-1273.351) IN NAÏVE AND PREVIOUSLY VACCINATED ADULTS

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STUDY TITLE

Protocol Number Code:	**DMID Protocol:21-0002 Cohort 2**
Development Phase:	Phase 1
Products:	mRNA-1273/mRNA-1273.351
Form/Route:	Injection
Indication Studied:	COVID-19
Sponsor:	Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health
Clinical Trial Initiation Date:	30MAR2021
Clinical Trial Completion Date:	Ongoing
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Version Number:	2.0

This study was performed in compliance with Good Clinical Practice.

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LIST OF ABBREVIATIONS

AE	Adverse Event
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
AUC	Area Under the Curve
BP	Blood Pressure
C	Celsius
CI	Confidence Interval
CRF	Case Report Form
DMID	Division of Microbiology and Infectious Diseases
EDC	Electronic Data Capture
ECLIA	Electro-chemiluminescence
ELISA	Enzyme-linked Immunosorbent Assay
F	Fahrenheit
FRNT	Focus Reduction Neutralization Test
GMT	Geometric Mean Titer
GMFR	Geometric Mean Fold Rise
ICH	International Council on Harmonisation
IRB	Institutional Review Board
LLN	Lower Limit of Normal
µg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
N	Number (typically refers to subjects)
NIH	National Institutes of Health
PI	Principal Investigator
PP	Per Protocol
PT	Preferred Term
RBC	Red Blood Cell
S-2P	S Protein in its Prefusion Conformation
SAE	Serious Adverse Event
SD	Standard Deviation
SDCC	Statistical and Data Coordinating Center

SMC	Safety Monitoring Committee
SOC	System Organ Class
SOP	Standard Operating Procedures
ULN	Upper Limit of Normal
WBC	White Blood Cell
WHO	World Health Organization

1. PREFACE

The Statistical Analysis Plan (SAP) for "Phase 1, Open-Label, Randomized Study of the Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine (mRNA-1273.351) in Naïve and Previously Vaccinated Adults" (DMID Protocol 21-0002) describes and expands upon the statistical information presented in the protocol for cohort 2 only. A separate SAP will be written for cohort 1. This document describes all planned analyses and provides reasons and justifications for these analyses. It also includes sample tables, listings, and figures planned for the final analyses. Regarding the final analyses and Clinical Study Report (CSR), this SAP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, as indicated in Topic E3 (Structure and Content of Clinical Study Reports), and more generally is consistent with Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials). The structure and content of the SAP provides sufficient detail to meet the requirements identified by the FDA and ICH, while all work planned and reported for this SAP will follow internationally accepted guidelines published by the American Statistical Association and the Royal Statistical Society for statistical practice.

This document contains a review of the study design, general statistical considerations, comprehensive statistical analysis methods for immunogenicity and safety outcomes, and a list of proposed tables, figures and listings. Within the table, figure, and listing mock-ups (Appendix 1, Appendix 2, and Appendix 3), references to CSR sections are included. The reader of this SAP is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

2. INTRODUCTION

An outbreak of COVID-19 caused by a novel SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019, and the disease has since spread globally [10]. The World Health Organization (WHO) declared COVID-19 a pandemic on 11 Mar 2020; however, widespread community transmission was already occurring in many locations. As of 14 Jan 2021, more than 92 million cases and 1.9 million deaths worldwide have been attributed to the COVID-19 pandemic [2,10].

ModernaTX, Inc has developed a vaccine platform based on the principle and observations that cells *in vivo* can take up mRNA, translate it, and then express protein viral antigen(s) on the cell surface. mRNA is highly precise in its translation into proteins that match viral antigens. The delivered mRNA does not enter the cell nucleus or interact with the genome, is nonreplicating, and is expressed transiently. The estimated half-life for mRNA after injection is approximately 8 to 10 hours, before degradation by native RNases in the body, but the duration of effect also depends on the half-life of the expressed protein, which persists in the body for several days. mRNA vaccines have been used to induce immune responses against infectious viral pathogens such as cytomegalovirus, human metapneumovirus, parainfluenza virus type 3, Zika, and influenza.

The mRNA-1273 encodes for the full-length spike (S) protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S protein (S-2P) in a prefusion conformation, derived from the Wuhan-Hu-1 strain [5]. The mRNA-1273 vaccine is currently being evaluated for safety and immunogenicity in a dose-ranging Phase 1 study sponsored by DMID (NCT04283461), for safety and immunogenicity in a Moderna-sponsored Phase 2a study (NCT04405076), and for safety, efficacy, and immunogenicity in a Moderna-sponsored Phase 3 study (NCT04470427). All three of these studies are ongoing and conducted in the US.

The primary efficacy objective of the Phase 3 study was met, with the vaccine efficacy of mRNA-1273 to prevent symptomatic COVID-19 disease observed to be 94.1%. The vaccine was also observed to be efficacious in preventing severe COVID-19. In December 2020 the FDA issued Emergency Use Authorization of mRNA-1273 (Moderna COVID-19 Vaccine) for active immunization to prevent COVID-19 in individuals 18 years of age and older.

Recently, SARS-CoV-2 variants with mutations in the S protein have emerged. A variant first identified in South Africa (B.1.351) is associated with increased transmission, higher viral burden, and possibly increased mortality in infected persons [8]. To date, four vaccines, all based on the Wuhan-sequence of the S protein, have shown reduced activity against the B.1.351 variant. Sera from individuals vaccinated with mRNA-based vaccines had a 6-to-9-fold reduction in neutralizing activity against a B.1.351-matched pseudovirion relative to a Wuhan-matched pseudovirion [9,11]. More recently, pivotal studies testing both viral vector and adjuvanted protein technologies had lower efficacy in regions where B.1.351 was known to be circulating [2]. Hence, the development and testing of vaccines targeting this SARS-CoV-2 variant is urgently needed.

mRNA-1273.351, like mRNA-1273, encodes the prefusion stabilized S protein of SARS-CoV-2. However, the mRNA of mRNA-1273.351 incorporates the key mutations present in the B.1.351 strain of the virus. This phase 1 clinical trial will evaluate the immunological benefit of boosting subjects previously vaccinated with mRNA-1273 (DMID 20-0003) with the B.1.351

strain-specific S protein, as well as the breadth of response induced by vaccinating with mRNA-1273 and mRNA-1273.351 in naïve persons, who have not previously received a SARS-CoV-2 vaccine and are not known to have been previously infected with SARS-CoV-2.

2.1. Purpose of the Analyses

These analyses will assess the immunogenicity and safety of mRNA-1273.351, given in vaccination schedules alone, sequentially, or co-administered with mRNA-1273 in naïve adults.

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives and Endpoints

OBJECTIVES	ENDPOINTS (OUTCOME MEASURES)
Primary	
• To evaluate the safety and reactogenicity of mRNA-1273 and mRNA-1273.351 vaccines, in naïve individuals.	• 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 any SAEs, Protocol Specified AESIs, NOCMCs, and MAAEs from the first vaccination through 12 months after the last vaccination.
Secondary	
• To assess humoral immunogenicity of mRNA-1273 and mRNA-1273.351 vaccines, in naïve individuals.	• Response rate, and magnitude of SARS-CoV-2-specific antibody binding and neutralization titers in serum samples as assessed via a range of assays at all timepoints.
Exploratory	
• To assess, in at least a subset of samples the innate immune response and B cell response following vaccination.	• Magnitude, phenotype, and percentage of innate immune cells and SARS-CoV-2 specific B cells, as measured by flow cytometry, and targeted B cell repertoire analysis at different timepoints post vaccination relative to baseline.
• 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 timepoints post vaccination relative to baseline.

3.2. Study Definitions and Derived Variables

For calculations using the baseline value, the value obtained pre-first vaccination (Day 1) will be used. For samples with an AUC of zero at baseline, fold-rise will be calculated by dividing the post-vaccination result by the lowest reported value. AUC is calculated using the trapezoidal method applied to a serial dilution curve.

The Williams mean is a variation of the geometric mean using log(1+x) transformation of the data, where x is each data point. The Williams mean is used in cases where 0 is a possible and/or reported value of the data.

4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

This is a phase 1, open-label, randomized clinical trial in males and non-pregnant females, 18 years of age and older, who are in good health, have no known history of COVID-19 or SARS-CoV-2 infection, and meet all other eligibility criteria. This clinical trial is designed to assess the safety, reactogenicity and immunogenicity of mRNA-1273.351 manufactured by ModernaTX, Inc, given in vaccination schedules alone, sequentially, or co-administered with mRNA-1273. mRNA-1273.351 is a novel LNP-encapsulated mRNA-based vaccine that encodes for a full-length, prefusion stabilized S protein of the SARS-CoV-2 B.1.351 variant. Enrollment will occur at approximately five domestic clinical research sites.

This study includes two cohorts. Cohort 1 will provide rapid information about the immunogenicity of mRNA-1273.351 in a previously vaccinated group. This cohort can inform near term public health decisions if the variant virus becomes more widespread. Cohort 2 will evaluate different strategies for generation of cross protective immune responses in a naïve population. This cohort will take longer to provide information on the immunogenicity of mRNA-1273.351, but is important to inform future public health strategies. As Cohorts 1 and 2 are in different populations, they can be enrolled in parallel as determined by each site.

Cohort 1 will include subjects 18 years of age and older who received two vaccinations of mRNA-1273 at dosages of 50 mcg, 100 mcg, or 250 mcg in the Phase 1 clinical trial (DMID 20-0003). Those subjects will be offered enrollment into this study approximately 9 to 12 months after they received the second vaccination in DMID 20-0003. At enrollment in this study, their long-term follow-up in DMID 20-0003 will be terminated. Subjects will be randomized, within each of the DMID 20-0003 cohorts (age and dosage groups – 50 mcg, 100 mcg, and 250 mcg), 1:1 to either:

- Arm 1A, vaccination with a 50-mcg dose of the mRNA-1273.351 variant, or
- Arm 1B, vaccination with a combination vaccination that includes 25 mcg of mRNA-1273 and 25 mcg of mRNA-1273.351.

The anticipated sample size to be drawn from the DMID 20-0003 study population is approximately 45 subjects 18 through 55 years of age and approximately 20 subjects 56 years of age and older.

Subjects in Cohort 1 will receive a single intramuscular (IM) injection of the designated vaccine and will be followed through 12 months after vaccination. Follow-up visits will occur on Days 8, 15, and 29, as well as 3, 6, and 12 months after the vaccination.

Cohort 2 will include approximately 150 participants 18 through 55 years of age who have not received a COVID-19 vaccine, have no known history of COVID-19 or SARS-CoV-2 infection, and do not have underlying conditions that are associated with an increased risk of severe illness from SARS-CoV-2 infection. Enrollment may close before the full 150 participants based on estimates on the timing of immunogenicity results and the need to inform public health decisions. They will be randomly assigned to one of 8 treatment arms and will receive 2 or 3 IM injections of the vaccine and followed through 12 months after the last vaccination (Table 1).

Follow-up visits will occur 7, 14, and 28 days after each vaccination, as well as 3, 6, and 12 months post the last vaccination.

For both Cohorts 1 and 2, reactogenicity will be assessed and blood will be drawn for immunogenicity assays.

After the IND is in effect, IRB review and approval, and site activation, the participating sites will begin recruitment outreach efforts, which can include fliers, letters, telephone calls, etc. Information regarding this trial may be provided to potential subjects who have previously participated in other vaccine trials conducted at the participating site. Other forms and/or mechanisms of recruitment may also be used. The IRB will approve the recruitment process and all materials prior to use. Screening can occur up to 42 days prior to the first dose.

4.2. Discussion of Study Design, Including the Choice of Control Groups

This phase 1 clinical trial is designed as an open-label study, without administration of a placebo formulation. An open-label study will facilitate the need for rapid review and dissemination of study data for public health reasons.

In the Phase 1 clinical trial, DMID 20-0003, mRNA-1273, administered as two injections 28 days apart, was investigated at dosages of 25, 50, 100 and 250 mcg in subjects 18 through 55 years of age, and at dosages of 25, 50, and 100 mcg in older cohorts (56-70 years of age and >71 years of age) [1,7]. The 100-mcg dose induced higher antibody titers than the 25-mcg dose, whereas the 250-mcg dose did not lead to significant increases, which supported evaluation of the 100-mcg dose in Phase 2 and Phase 3 trials. Subsequent to the start of the Phase 3 trial, an interim analysis of immunogenicity data from the Phase 2 demonstrated that the 50 and 100-mcg doses in a two-dose series are similarly immunogenic [4] and warrants further evaluation. The primary efficacy analysis from the Phase 3 trial evaluating a two-dose schedule of a 100-mcg mRNA-1273 vaccine led to the issuance of the EUA and initiation of a vaccination campaign in the United States.

The Phase 2 trial of mRNA-1273 evaluated doses of 50 mcg and 100 mcg, administered as a two-vaccination series, in 600 adults ≥18 years of age. The safety profile of both formulations was acceptable [4]. Anti-SARS-CoV-2 S binding and neutralizing antibodies were induced by both dose levels of mRNA-1273 within 28 days after the first vaccination, and rose substantially to peak titers by 14 days after the second vaccination, exceeding levels of convalescent sera from COVID-19 patients. The antibodies remained elevated through the last timepoint assessed at 57 days. Neutralizing responses met criteria for seroconversion within 28 days after the first vaccination in the majority of participants, with rates of 100% observed at 14 and 28 days after the second vaccination. Binding and neutralizing antibody responses were generally comparable in participants who received the 100 mcg mRNA-1273 and the 50 mcg dose at all time points and across the age groups of ≥18 to <55 years and ≥55 years. These findings support the evaluation of mRNA-1273 and mRNA-1273.351 at total dosages of 50 or 100 mcg per vaccination.

4.3. Selection of Study Population

Two cohorts will be enrolled. For Cohort 1, approximately 60 males and non-pregnant female subjects 18 years of age and older, who are in good health and received two vaccinations of mRNA-1273 at dosages of 50 mcg, 100 mcg or 250 mcg in DMID 20-0003 will be invited to participate in this study.

For Cohort 2, approximately 150 males and non-pregnant females, 18 through 55 years of age, who have never been vaccinated against SARS-CoV-2 or are not known to have been infected with SARS-CoV-2, and are at low risk for severe disease, in good health, and meet all eligibility criteria will be enrolled. The target population should reflect the community at large.

The estimated time from initiation of enrollment to complete enrollment in this clinical trial is approximately 4 weeks (though could take up to 8 weeks). Information regarding this trial may be provided to potential subjects who have previously participated in other vaccine trials conducted at the participating site. Other forms and/or mechanisms of recruitment may also be used. The IRB will approve the recruitment process and all materials prior to use. Screening can occur up to 42 days prior to the first vaccination.

Subject Inclusion and Exclusion Criteria must be confirmed by a study clinician, licensed to make medical diagnoses and listed on the Form FDA 1572 as the participating site principal investigator (PI) or appropriate sub-investigator. No exemptions are granted on Subject Inclusion or Exclusion Criteria in DMID-sponsored studies.

Inclusion Criteria

A subject must meet all the following criteria to be eligible to participate in this study:

1. Provides written informed consent prior to initiation of any study procedures.
2. Be able to understand and agrees to comply with planned study procedures and be available for all study visits.
3. Agrees to the collection of venous blood per protocol.
4. Cohort 1: previously received 2 doses of mRNA-1273 IM as part of DMID 20-0003.
5. Cohort 1: Male or non-pregnant female, ≥18 years of age at time of enrollment.

   Cohort 2: Male or non-pregnant female, 18 through 55 years of age at time of enrollment.
6. Women of childbearing potential[1] must agree to practice abstinence or use at least one acceptable primary form of contraception.[2,3]

Note: These criteria are applicable to females in a heterosexual relationship and child-bearing potential (i.e., the criteria do not apply to subjects in a same sex relationship).

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

[2]Acceptable forms of primary contraception include monogamous relationship with a vasectomized partner who has been vasectomized for 180 days or more prior to the

subject's first vaccination, intrauterine devices, birth control pills, and injectable/implantable/insertable hormonal birth control products.

[3]*Must use at least one acceptable primary form of contraception for at least 30 days prior to the first vaccination and at least one acceptable primary form of contraception for 60 days after the last vaccination.*

7. In good health.[4]

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

8. Oral temperature is less than 100.0°F (37.8°C).
9. Must agree to have samples stored for secondary research.
10. Agrees to adhere to Lifestyle Considerations (defined in Section 5.4 of the Protocol) throughout study duration.
11. Must agree to refrain from donating blood or plasma during the study (outside of this study).

Exclusion Criteria

A subject who meets any of the following criteria will be excluded from participation in this study:

1. Positive pregnancy test prior to each vaccine administration.
2. BMI >40.0 kg/m^2.
3. Female subject who is breastfeeding.
4. Has any medical disease or condition that, in the opinion of the participating site PI or appropriate sub-investigator, precludes study participation.[5]

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

5. Presence of self-reported or medically documented significant medical or psychiatric condition(s).[6]

[6]*Significant medical or psychiatric conditions include but are not limited to:*

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

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

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

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

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

An immunodeficiency of any cause.

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

Type 2 diabetes mellitus, not including prediabetes.

6. Has an acute illness[7], as determined by the participating site PI or appropriate sub-investigator, with or without fever [oral temperature ≥38.0°C (100.4°F)] within 72 hours prior to each vaccination.

[7]*An acute illness which is nearly resolved with only minor residual symptoms remaining is allowable if, in the opinion of the participating site PI or appropriate sub-investigator, the residual symptoms will not interfere with the ability to assess safety parameters as required by the protocol.*

7. Has participated in another investigational study involving any investigational product[8] within 5 half-lives before the first vaccine administration.

[8]*Study drug, biologic or device*

8. Currently enrolled in or plans to participate in another clinical trial with an investigational agent[9] that will be received during the study-reporting period.[10]

[9]*Including licensed or unlicensed vaccine, drug, biologic, device, blood product, or medication.*

[10]*Up to 15 months after the first vaccination.*

9. Has a history of hypersensitivity or severe allergic reaction (e.g., anaphylaxis, generalized urticaria, angioedema, other significant reaction) to drugs or any previous licensed or unlicensed vaccines or to polyethylene glycol (PEG) or a PEG-containing product.
10. Chronic use (more than 14 continuous days) of any medications that may be associated with impaired immune responsiveness.[11]

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

11. Anticipating the need for immunosuppressive treatment within the next 6 months.
12. Received immunoglobulins and/or any blood or blood products within the 4 months before the first vaccine administration or at any time during the study.
13. Has any blood dyscrasias or significant disorder of coagulation.
14. Received or plans to receive a licensed, live vaccine within 4 weeks before or after each vaccination.
15. Received or plans to receive a licensed, inactivated vaccine within 2 weeks before or after each vaccination.
16. Receipt of any other SARS-CoV-2 vaccine or any experimental coronavirus vaccine at any time prior to or during the study, except Cohort 1 subjects who received mRNA-1273 in DMID 20-0003.
17. Close contact of anyone known to have SARS-CoV-2 infection within 14 days prior to vaccine administration.
18. History of COVID-19 diagnosis, positive SARS-CoV-2 PCR test, or, for Cohort 2 only, a known positive SARS-CoV-2 serologic test.
19. On current treatment with investigational agents for prophylaxis of COVID-19.

4.4. Treatments

4.4.1. Treatments Administered

Eight treatment arms administering various combinations of mRNA-1273 and mRNA-1273.351 (Table 1).

Summary of Treatment Arms:

- 2A: Evaluates the mRNA-1273 EUA vaccination series, plus a variant vaccine as a third dose.
- 2B: Evaluates a 50-mcg mRNA-1273 vaccination series, plus a variant vaccine as a third dose.
- 2C: Evaluate 2 doses of the homologous variant vaccine at 100mcg.
- 2D: Evaluate 2 doses of the homologous variant vaccine at 50mcg.
- 2E: Evaluate heterologous prime-boost strategies at 100mcg.
- 2F: Evaluate heterologous prime-boost strategies at 50mcg.
- 2G: Evaluate a 1:1 mix of vaccine (2 doses), with the total dose for both vaccines equal to 100 mcg.
- 2H: Evaluate a 1:1 mix of vaccine (2 doses), with the total dose for both vaccines equal to 50 mcg.

4.4.2. Identity of Investigational Product(s)

Product: There are two clinical presentations of mRNA-1273 — mRNA-1273 and mRNA-1273.351

mRNA-1273 (0.2 mg/mL) is an LNP dispersion containing an mRNA that encodes for the pre fusion stabilized S protein of the Wuhan-Hu-1 strain of SARS-CoV-2. mRNA-1273 consists of an mRNA Drug Substance that is manufactured into LNPs composed of the proprietary ionizable lipid, SM-102, and 3 commercially available lipids, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), and PEG2000 DMG.

mRNA-1273.351 (0.5 mg/mL) is formulated in the same way but contains mRNA that encodes for the prefusion stabilized S protein of the B.1.351 variant SARS-CoV-2 strain.

4.4.3. Method of Assigning Subjects to Treatment Groups (Randomization)

Subjects in Cohort 2 will be randomized in a ratio of 3:3:4:4:4:4:4:4 to Arms 2A-H. Randomization will be done in the SDCC's Advantage eClinical^{SM} (Electronic Data Capture System).

4.4.4. Selection of Dose in the Study

See Section 4.2 for a discussion of dose selection for this study.

4.4.5. Prior and Concomitant Therapy

Concomitant medications include only prescription medications and vaccines received outside of the study taken by the subject at the time of enrollment through 28 days after the last vaccination. At each study visit, if there are new SAEs, Protocol Specified AESIs, MAAEs, or NOCMCs, concomitant medications should be recorded on the appropriate DCF.

4.4.6. Treatment Compliance

All subjects are to receive 2 (Arms 2C-H) or 3 (Arms 2A-B) doses of study product administered in the clinic. The number of doses received will be reported in Table 7 (Arms 2A-B) and Table 8 (Arms 2C-H).

5. SAMPLE SIZE CONSIDERATIONS

Rare AEs are not demonstrable in a clinical study of this size; however, the probabilities of observing one or more AEs given various true event rates are presented in Table 4. With the assumption that all enrolled subjects will likely complete immunizations and safety visits in this relatively short duration study, the following statistical considerations apply. With 15 subjects in Arms 2A and 2B, the chance of observing at least one AE of probability 20% or more is approximately 97%. Therefore, if no AEs of a given type occur in Arms 2A or 2B, we can be relatively confident that they will occur in fewer than 20% of people once the vaccine is implemented. With 20 subjects in each arm (Arms 2C-2H), the chance of observing at least one AE of probability 20% or more is approximately 99%. Therefore, if no AEs of a given type occur in Arms 2C-2H, we can be relatively confident that they will occur in fewer than 20% of people once the vaccine is implemented. With approximately 150 subjects across these eight Arms (2A-2H), the chance of observing at least one AE of probability 3% or more is at least 99%. Therefore, if no AEs of a given type occur across Cohort 2, we can be very confident that any dosage/combination independent event will occur in fewer than 3% of people once the vaccine is implemented.

6. GENERAL STATISTICAL CONSIDERATIONS

6.1. General Principles

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

6.2. Analysis Populations

6.2.1. Safety Population

The Safety Analysis population includes all subjects who received one dose of the vaccine.

6.2.2. Modified Intent-to Treat Population

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

6.2.3. Per Protocol Population

In the final analysis, protocol deviations will be reviewed to determine which protocol deviations may affect the analysis. The per protocol (PP) population will then be defined – and this includes all subjects in the mITT subset with the following exclusions:

- Data from all available visits for subjects found to be ineligible at baseline.
- Data from all visits subsequent for the protocol deviations that are considered to affect the science.
- Data from any visit that occurs substantially out of window.

6.3. Covariates and Subgroups

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

6.4. Missing Data

There are no imputations planned for missing data.

For immunogenicity assays, any values below the lower limit of detection will be imputed as one-half the lower limit of detection for analysis purposes. Any such imputations will be noted in the corresponding analysis.

6.5. Interim Analyses and Data Monitoring

Cumulative safety information, study status, and primary endpoint results may be published, presented at a public forum, or presented as summaries aggregated by study arm at the discretion of the sponsor while the study is ongoing. Any ad-hoc analyses, jointly developed by the SDCC and/or the Vaccine Research Center (VRC), other participating laboratories and ModernaTX, Inc., will be executed by the SDCC as needed. None of the interim analyses will include any formal statistical hypothesis testing; therefore, p-value adjustment will not be made to any analyses.

The SMC will not need to meet (unless halting rules are met), and materials will be provided electronically. Documentation of review and any concerns noted will be solicited electronically. The SMC will review cumulative AE data after all subjects in Cohort 1 have been dosed and completed Day 8.

Interim data review of immunogenicity may be performed to inform public health decisions.

Statistical analyses of secondary immunogenicity endpoints, by vaccine schedule group, may be performed when subjects have completed key immunogenicity visits. Immunogenicity reviews may be shared with the SMC, as determined by DMID.

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

Interim analyses of safety, reactogenicity, and immunologic response data may be done, as needed.

6.6. Multicenter Studies

Data will be pooled across all clinical sites. Center effects are not anticipated because the sites are using standardized procedures for vaccination and assessment of solicited and unsolicited adverse events, and the study relies on central laboratories for the assessment of immunogenicity endpoints.

6.7. Multiple Comparisons/Multiplicity

There are no adjustments planned for multiple comparisons.

7. STUDY SUBJECTS

7.1. Disposition of Subjects

Table 11 will present a summary of the reasons that subjects were screened but not enrolled.

The composition of analysis populations, including reasons for subject exclusion, by treatment arm, is presented in Table 9 and Table 10.

The disposition of subjects in the study will be tabulated by treatment group (Table 7 and Table 8). The tables show the total number of subjects screened, enrolled, receiving the first vaccination, receiving second vaccination, receiving third vaccination (Arms 2A-B), terminated from study follow-up, and the number completing the study.

A flowchart showing the disposition of study subjects, adapted from the Consort Statement [5] will be included (Figure 1). This figure will present the number of subjects screened, enrolled, lost to follow-up, and analyzed, by treatment group.

A listing of subjects who discontinued dosing or terminated from study follow-up and the reason will be included in Listing 2.

7.2. Protocol Deviations

A summary of subject-specific protocol deviations will be presented by the reason for the deviation, the deviation category, and treatment group for all subjects (Table 5) as well as similar summaries for major subject-specific protocol deviations (Table 6). All subject-specific protocol deviations and non-subject specific protocol deviations will be included in Appendix 3 as data listings (Listing 3 and Listing 4, respectively).

8. IMMUNOGENICITY EVALUATION

8.1. Primary Immunogenicity Analysis

See Section 9 for safety analyses which are the primary endpoints of this study.

8.2. Secondary Immunogenicity Analyses

Summaries and analysis of immunogenicity data will be presented for the mITT population. If there are protocol deviations which may affect the analysis, a per-protocol (PP) analysis may also be performed.

Seropositive is defined as above LLOD (if available).

Binding will be measured by three types of ECLIA assays. The first is a single-plex (ECLIA) that produces arbitrary units/mL that is a validated assay and can be converted to binding antibody units for Wa-1 S-2P binding. The second is a 4-plex (ECLIAv2) assay that is also validated and produces arbitrary units/mL to measure variant specific binding. The final assay is a 10-plex (ECLIAv2) that is a fit for purpose assay that produces area under the curve and is used to assess binding for variants of concern.

Seropositive rates, geometric mean fold rise (GMFR) and geometric mean (GM) or Williams mean of arbitrary units per mL (AU/mL), binding antibody unit/mL (BAU, only for Wa-1 [S2-P] variant), and AUC for SARS-CoV-2 will be calculated at Study Days 1 (GM only), 15, 29, 43, 57, 71, 85, 147, 237, and 422 (Arms 2A-B) and Days 1, 15, 29, 43, 57, 119, 209, 394 (Arms 2C-H) by treatment group and will include both tabular and graphical summaries. Seropositive rates, GMFR, and GM will be presented with their corresponding 95% confidence interval (CI) estimates (using Student's t-distribution for GM and GMFR and the Clopper-Pearson binomial method for seropositive) at each post vaccination timepoint and overall peak GM. Summaries of GM are included starting with Table 15 and ending with Table 62; and summaries of GMFR and seroconversion are included starting with Table 191 and ending with Table 238. Graphical displays will include reverse cumulative distribution plots (starting with Figure 2, ending with Figure 25; and starting with Figure 86, ending with Figure 109), individual values over time (starting with Figure 170, ending with Figure 193; and starting with Figure 254, ending with Figure 277), geometric mean over time (starting with Figure 338, ending with Figure 361; and starting with Figure 422, ending with Figure 445), and distribution of responses over time (starting with Figure 506, ending with Figure 529; and starting with Figure 590, ending with Figure 613).

Neutralization assays using SARS-CoV-2 pseudovirus neutralization assay (PsVNA) and focus reduction neutralization test (FRNT) will be run using serial dilutions against available variants (e.g., Beta, Delta, Omicron). ID_{50} and ID_{80} will be calculated using methodology such as a 5-parameter logistic regression model by the laboratory. ID_{50} and ID_{80} will be summarized by group using the geometric mean and 95% CI (using Student's t-distribution) at each post vaccination timepoint and overall peak GM (starting with Table 63 and ending with Table 182). Summaries of GMFR and seropositive are included starting with Table 239 and ending with Table 358. The ratio of the result for each variant divided by the result of the D614G variant will be calculated and summarized as the geometric mean ratio (GMR) (starting with Table 359 and ending with Table 382). Graphical displays for PsVNA and FRNT will include reverse

cumulative distribution plots (starting with Figure 26, ending with Figure 85; and starting with Figure 110, ending with Figure 169), individual values over time (staring with Figure 194, ending with Figure 253; and starting with Figure 278, ending with Figure 337), geometric mean over time (starting with Figure 362, ending with Figure 421; and starting with Figure 446, ending with Figure 505) and distributions of responses over time (starting with Figure 530, ending with Figure 589; and starting with Figure 614, ending with Figure 673).

Correlations between all assays will be displayed in a heatmap (staring with Figure 674 and ending with Figure 697).

Summaries of N-antibody expression status and self-reported infection status will be reported in Table 383, Table 384, Table 385, and Table 386.

Individual immunogenicity responses are shown in Listing 8.

Any additional variants of concern not listed in the appendices that are of scientific interest may be analyzed in an analogous manner in the final report.

8.3. Exploratory Immunogenicity Analyses

The magnitude, phenotype and percentage of cytokine expressing S protein specific T cells will be summarized at each timepoint by Treatment Group. Mean percentages of CD4 and CD8 T cells expressing cytokines and proportions of responders with 95% CI along with median, minimum, and maximum will be presented by peptide pool stimulation (Table 183, Table 184, Table 185, Table 186, Table 187, Table 188, Table 189, and Table 190). Distributions of T cell percentages will be graphically displayed (starting with Figure 698 and ending with Figure 1249).

Individual T-cell responses are shown in Listing 9.

9. SAFETY EVALUATION

Summaries and analysis of safety data will be presented for the Safety Analysis Population.

Solicited AEs will be summarized by severity for each day post vaccination (Days 1-8) for each dose and as the maximum severity over all 8 days. Additionally, solicited AEs will be analyzed by taking the most severe response over the follow-up period and using standard techniques, such as exact confidence intervals (CI), to summarize the proportion of subjects reporting each symptom, any local symptom, and any systemic symptom.

Unsolicited non-serious AEs will be collected from the time of the first vaccination through 28 days after the final vaccination. Unsolicited AEs will be coded by MedDRA for preferred term and system organ class (SOC). SAEs, Protocol Specified AESIs, MAAEs, and NOCMCs will be collected from the time of first vaccination through 12 months after the final vaccination. The numbers of SAEs and MAAEs will be reported by detailed listings showing the event description, MedDRA preferred term and SOC, relevant dates (vaccinations and AEs), severity, relatedness, and outcome for each event. Non-serious unsolicited AEs will be summarized as number and percentage of subjects reporting at least one event in each MedDRA preferred term and SOC, cross tabulated by severity and relationship to study product. Additionally, the proportion of subjects and exact 95% CIs of AEs in aggregate and by MedDRA categories will be computed.

9.1. Demographic and Other Baseline Characteristics

Summaries of age, sex, ethnicity, and race will be presented by Treatment Group (Table 12 and Table 13). Ethnicity is categorized as Hispanic or Latino, or not Hispanic and not Latino. In accordance with NIH reporting policy, subjects may self-designate as belonging to more than one race or may refuse to identify a race, the latter reflected in the CRF as "No" to each racial option. Prior infection status by N-antibody will also be included.

Individual subject listings will be presented for all demographics (Listing 6).

9.1.1. Prior and Concurrent Medical Conditions

All current illnesses and past pre-existing medical conditions will be MedDRA® coded using MedDRA dictionary version 23.0r higher.

Summaries of subjects' pre-existing medical conditions will be presented by Treatment Group (Table 14).

Individual subject listings will be presented for all medical conditions (Listing 7).

9.1.2. Prior and Concomitant Medications

Summaries of medications that were started prior to dosing and continuing at the time of dosing will be presented by WHO Drug Terms 2 and 3 and Treatment Group (Table 425).

Individual subject listings will be presented for all concomitant medications (Listing 15).

9.2. Measurements of Treatment Compliance

All subjects are to receive 2 (Arms 2C-H) or 3 (Arms 2A-B) doses of study product administered in the clinic. The number of subjects receiving each dose will be summarized as part of the subject disposition table (Table 7 and Table 8).

9.3. Adverse Events

When calculating the incidence of adverse events (i.e., on a per subject basis), each subject will only be counted once and any repetitions of adverse events within a subject will be ignored; the denominator will be the total population size. All adverse events reported will be included in the summaries and analyses.

9.3.1. Solicited Events and Symptoms

Systemic solicited adverse events were collected pre-vaccination, and systemic and local solicited adverse events were collected 30 minutes post-vaccination and then daily for 7 days after the vaccination and graded on a scale of 0 (absent), 1 (mild), 2 (moderate) and 3 (severe). Systemic events include: fatigue, headache, myalgia, arthralgia, nausea, chills and fever. Local events include: pain at injection site, erythema, and induration.

For each systemic and local event, any systemic event, any local event, and any solicited event, the maximum severity over 7 days after the third vaccination will be summarized for the Safety population. The number and percentage of subjects reporting each event will be summarized by the maximum severity and treatment group (Table 389). For each event the denominator is the number of subjects with non-missing data for the specific event.

The number of subjects reporting a solicited adverse event will be summarized for each day post-vaccination both in a summary table (staring with Table 390 and ending with Table 407) and graphically in a bar chart (Figure 1250, Figure 1251, Figure 1252, Figure 1253, Figure 1254, and Figure 1255).

The mean, standard deviation, median, minimum and maximum duration of solicited events will be summarized (Table 408).

Day of solicited symptom onset will be summarized graphically (Figure 1256, Figure 1257, Figure 1258, Figure 1259, Figure 1260, and Figure 1261).

Solicited adverse events by subject will be presented in listings (Listing 10 and Listing 11) and graphically (starting with Figure 1262 and ending with Figure 1275).

9.3.2. Unsolicited Adverse Events

The proportion of subjects reporting at least one unsolicited adverse event will be summarized by MedDRA system organ class and preferred term. Denominators for percentages are the number of subjects who received the vaccination.

Adverse events by subject will be presented in Listing 12.

The following summaries for unsolicited adverse events will be presented by MedDRA system organ class, preferred term, and Treatment Group:

- Subject incidence and total frequency of adverse events (Table 409);
- Summary of severity and relationship to study product (Table 410 and Table 411);
- Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events (Table 412);
- Bar chart of frequency of adverse events by severity and MedDRA system organ class (Figure 1274);
- Bar chart of incidence of adverse events by severity and MedDRA system organ class (Figure 1275).

9.4. Deaths, Serious Adverse Events and other Significant Adverse Events

The following listings will be presented including Subject ID, Age (years) Adverse Event Description, Adverse Event Onset Date/End Date, Last Dose Received/Days Post Dose, Reason Reported as an SAE, Relationship to Treatment, Alternate Etiology if not Related, Outcome, and Duration of Event (days):

- Deaths and Serious Adverse Events (Table 412);
- Adverse Events of Special Interest, New Onset Chronic Medical Conditions and Medically Attended Adverse Events (Table 414).

9.5. Pregnancies

For any subjects in the Safety population who became pregnant during the study, every attempt will be made to follow these subjects to completion of pregnancy to document the outcome, including information regarding any complications with pregnancy and/or delivery. A listing of pregnancies and outcomes will be presented (Listing 16, Listing 17, Listing 18, Listing 19, and Listing 20).

9.6. Clinical Laboratory Evaluations

Not applicable.

9.7. Vital Signs and Physical Evaluations

Vital sign measurements included systolic blood pressure, diastolic blood pressure, pulse, and oral temperature. Vital signs were assessed at Study Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422 (Arms 2A-B) and Study Days 1, 15, 29, 43, 57, 119, 209, and 394 (Arms 2C-H). Vital signs will be tabulated by visit and Treatment Group starting with Table 415 and ending with Table 424 (Listing 13).

Physical Examinations were only to be performed if clinically indicated at Study Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422 (Arms 2A-B) and Study Days 1, 15, 29, 43, 57, 119, 209, and 394 (Arms 2C-H). The following body systems will be assessed: Abdomen, Cardiovascular/heart, Extremities, General Appearance, Hepatobiliary/spleen, HEENT, Lymph nodes, Musculoskeletal, Neck, Neurological, Pulmonary/Chest, and Skin (Listing 14).

9.8. Concomitant Medications

Concomitant medications will be coded to the Anatomical Therapeutic Classification using the WHO Drug Dictionary. The use of prior and concomitant medications taken during the study will be recorded on the CRFs. A by-subject listing of concomitant medication use will be presented (Listing 15). The use of concomitant medications during the study will be summarized by ATC1, ATC2 code and Treatment Group for the Safety population (Table 425).

9.9. Other Safety Measures

Not applicable.

10. PHARMACOKINETICS

Not applicable.

11. IMMUNOGENICITY

See Section 8.

12. OTHER ANALYSES

Not Applicable.

13. REPORTING CONVENTIONS

The mean, standard deviation, and other statistics will be reported to 1 decimal place greater than the original data. The minimum and maximum will use the same number of decimal places as the original data. Proportions will be presented as 2 decimal places; values greater than zero but <0.01 will be presented as "<0.01". Percentages will be reported to the nearest whole number; values greater than zero but < 1% will be presented as "<1"; values greater than 99% but less than 100% will be reported as >99%. Estimated parameters, not on the same scale as raw observations (e.g., regression coefficients) will be reported to 3 significant figures.

14. TECHNICAL DETAILS

SAS version 9.4 and R 3.6.2 or above will be used to generate all tables, figures and listings.

15. SUMMARY OF CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

Not Applicable.

16. REFERENCES

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APPENDIX 1. TABLE MOCK-UPS

LIST OF TABLES

9.1 Overall Study Design and Plan Description

Table 1: Study Design

Arm	Sample Size	First Vaccination	Second Vaccination		Third Vaccination	
		Product and Dose	Interval	Product and Dose	Interval	Product and Dose
2A	15	100 mcg mRNA-1273	28 days	100 mcg mRNA-1273	28 days	50 mcg mRNA-1273.351
2B	15	50 mcg mRNA-1273	28 days	50 mcg mRNA-1273	28 days	50 mcg mRNA-1273.351
2C	20	100 mcg mRNA-1273.351	28 days	100 mcg mRNA-1273.351	None	
2D	20	50 mcg mRNA-1273.351	28 days	50 mcg mRNA-1273.351	None	
2E	20	100 mcg mRNA-1273	28 days	100 mcg mRNA-1273.351	None	
2F	20	50 mcg mRNA-1273	28 days	50 mcg mRNA-1273.351	None	
2G	20	50 mcg mRNA-1273 + 50 mcg mRNA-1273.351	28 days	50 mcg mRNA-1273 + 50 mcg mRNA-1273.351	None	
2H	20	25 mcg mRNA-1273 + 25 mcg mRNA-1273.351	28 days	25 mcg mRNA-1273 + 25 mcg mRNA-1273.351	None	

9.5.1 Efficacy/Immunogenicity and Safety Measurements Assessed and Flow Chart

Table 2: Schedule of Study Procedures for Treatment Arms 2A-B (Three Vaccinations)

Study Day	-42 to -1	1	8*	15	29	36*	43	57	64*	71	85	147	237	422	Unsc Visit	Early Term Visit
Visit Window (±number of days)		0	1	2	2	1	2	2	1	2	2	7	7	14		
Study Visit	Screening (optional) 00	01	02	03	04	05[e]	06[e]	07[e]	08[f]	09[f]	10[f]	11[f]	12[f]	13[f]		
Informed Consent	X	X[a]														
Review Eligibility Criteria	X	X														
Medical History	X	X[a]														
Vaccination		X			X			X								
Concomitant Medications		X	X	X	X	X	X	X	X	X	X					
Interim History		X[b]		X	X		X	X		X	X	X	X	X	X	X
Symptom-Directed Physical Examination	X	X		X	X		X	X		X	X	X	X	X	X	X
Vital Signs[c]		X		X	X		X	X		X	X	X	X	X	X	X
Height and Weight (for BMI)	X	X[a]														
Pregnancy Test[d]		X			X			X								
Memory Aid: Solicited AEs		X	X	X[g]	X	X	X[g]	X	X	X[g]						
Unsolicited AEs		X	X	X	X	X	X	X	X	X	X					
SAEs, Protocol Specified AESIs, MAAEs, and NOCMCs		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum for Serological Immunogenicity Assays		X		X	X		X	X		X	X	X	X	X		X
Peripheral Blood Mononuclear Cells (PBMCs) for Cellular Immunology Assays (and Plasma)		X		X	X		X	X		X			X	X		X

* Telephone call.

a) If not performed at Visit 00.
b) If medical history performed at Visit 00, then interim history at Visit 01.
c) Vital signs to be obtained pre and post vaccination. Otherwise, only as clinically indicated.
d) For women of childbearing potential, a negative urine pregnancy test on Day 1 with results confirmed prior to enrollment.
e) Visits 05-07 windows should be based off the actual Visit 04 date.
f) Visits 08-13 windows should be based off the actual Visit 07 date.
g) Collect Memory Aid and assess for delayed onset local reactions.

Table 3: Schedule of Study Procedures for Treatment Arms 2C-H (Two Vaccinations)

Study Day	-42 to -1	1	8*	15	29	36*	43	57	119	209	394	Unsc Visit	Early Term Visit
Visit Window (±number of days)		0	1	2	2	1	2	2	7	7	14		
Study Visit	Screening (optional) 00	01	02	03	04	05[e]	06[e]	07[e]	08[e]	09[e]	10[e]		
Informed Consent	X	X[a]											
Review Eligibility Criteria	X	X											
Medical History	X	X[a]											
Vaccination		X			X								
Concomitant Medications		X	X	X	X	X	X	X					
Interim History		X[b]		X	X		X	X	X	X	X	X	X
Symptom-Directed Physical Examination	X	X		X	X		X	X	X	X	X	X	X
Vital Signs[c]		X		X	X		X	X	X	X	X	X	X
Height and Weight (for BMI)	X	X[a]											
Pregnancy Test[d]		X			X								
Memory Aid: Solicited AEs		X	X	X[f]	X	X	X[f]						
Unsolicited AEs		X	X	X	X	X	X	X					
SAEs, Protocol Specified AESIs, MAAEs, and NOCMCs		X	X	X	X	X	X	X	X	X	X	X	X
Serum for Serological Immunogenicity Assays		X		X	X		X	X	X	X	X		X
Peripheral Blood Mononuclear Cells (PBMCs) for Cellular Immunology Assays (and Plasma)		X		X	X		X			X	X		X

* Telephone call.

a) If not performed at Visit 00.
b) If medical history performed at Visit 00, then interim history at Visit 01.
c) Vital signs to be obtained pre and post vaccination. Otherwise, only as clinically indicated.
d) For women of childbearing potential, a negative urine pregnancy test on Day 1 with results confirmed prior to enrollment.
e) Visits 05-10 windows should be based off the actual Visit 04 date.
f) Collect Memory Aid and assess for delayed onset local reactions.

9.7.1 Sample Size

Table 4: Sample Size/Probability Estimates

Cohort 2								
N	**"True" Event Rate**	**Probability of Observation (%)**	**N**	**"True" Event Rate**	**Probability of Observation (%)**	**N**	**"True" Event Rate**	**Probability of Observation (%)**
15	0.1%	1.5	20	0.1%	2.0	150	0.1%	13.9
	0.5%	7.2		0.5%	9.5		0.5%	52.9
	1.0%	14.0		1.0%	18.2		1.0%	77.9
	2.0%	26.1		2.0%	33.2		2.0%	95.2
	3.0%	36.7		3.0%	45.6		3.0%	99.0
	4.0%	45.8		4.0%	55.8		4.0%	99.8
	5.0%	53.7		5.0%	64.2		5.0%	>99.9
	10.0%	79.4		10.0%	87.8		10.0%	>99.9
	15.0%	91.3		15.0%	96.1		15.0%	>99.9
	20.0%	96.5		20.0%	98.8		20.0%	>99.9

10.2 Protocol Deviations

Table 5: Distribution of Protocol Deviations by Category, Type, and Treatment Group

[Implementation Note: Below are example categories and deviation types. All reported categories and deviations types will be presented.]

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Category	**Deviation Type**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**
Follow-up visit schedule	**Missed visit/visit not conducted**																		
	Out of window visit																		
Protocol procedure/assessment	**Other: breach of confidentiality**																		
	Other: non-required lab tests performed																		
	Required procedure done incorrectly																		
	Required procedure not conducted																		
	Specimen result not obtained																		
	Too few aliquots obtained																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Category	**Deviation Type**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**
Treatment administration schedule	**Required procedure done incorrectly**																		
Note: N=Number of subjects in the Safety Population																			

Table with Similar Format:

Table 6: Distribution of Major Protocol Deviations by Category, Type, and Treatment Group

14.1 Description of Study Subjects

14.1.1 Disposition of Subjects

Table 7: Subject Disposition by Treatment Group for Arms 2A-B (Three Vaccinations)

	Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**
Screened						
Enrolled						
Received dose 1						
Received dose 2						
Received dose 3						
Early termination[a]						
Completed study						

[a]Refer to Listing 2 for reasons subjects discontinued or terminated early.
Note: N=Number of subjects in the Safety Population

Table 8: Subject Disposition by Treatment Group for Arms 2C-H (Two Vaccinations)

	Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Subject Disposition	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Screened														
Enrolled														
Received dose 1														
Received dose 2														
Early termination[a]														
Completed study														

[a]Refer to Listing 2 for reasons subjects discontinued or terminated early.
Note: N=Number of subjects in the Safety Population

Table 9: Analysis Populations by Treatment Group - Treatment Arms 2A-B (Three Vaccinations)

Analysis Populations	Reason Subjects Excluded	Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
		%	n	%	n	%	n
Safety	Did not receive one dose of the vaccine	x	xx	x	xx	x	xx
Modified Intent-To-Treat	Any Reason						
	Did not contribute a pre-vaccination blood sample for which valid immunogenicity results were reported						
	Did not contribute at least one post-vaccination blood sample for which valid immunogenicity results were reported						
Per Protocol	**Any Timepoint**						
	Found to be ineligible at baseline[a]						
	Protocol deviation considered to affect the science[b]						
	Visit occurred substantially out of window[c]						
	Prior to or at Day 1 visit (visit 01):						
	Found to be ineligible at baseline[a]						
	Protocol deviation considered to affect the science[b]						
	Visit occurred substantially out of window[c]						
	Repeat Day 1 for:						

Analysis Populations	Reason Subjects Excluded	Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
		%	n	%	n	%	n
	Prior to or at Day 15 visit (visit 03):						
	Prior to or at Day 29 visit (visit 04):						
	Prior to or at Day 43 visit (visit 06):						
	Prior to or at Day 57 visit (visit 07):						
	Prior to or at Day 71 visit (visit 09):						
	Prior to or at Day 85 visit (visit 10):						
	Prior to or at Day 147 visit (visit 11):						
	Prior to or at Day 237 visit (visit 12):						
	Prior to or at Day 422 visit (visit 13):						

Notes: N=Number of subjects enrolled.
n=Number of subjects meeting the criteria.

Subjects may be excluded from an analysis population for multiple reasons.

[a] Subject data from all visits are excluded from the per protocol analyses. All instances of exclusion are summarized in this table.

[b] Subject data are excluded from the per protocol analyses at all timepoints subsequent to the occurrence of this protocol deviation. All instances of exclusion are summarized in this table. Subject data collected up to the time the exclusionary criterion is met is eligible for analysis.

[c] Only data from the out of window visit are excluded from the per protocol analyses.

Table 10: Analysis Populations by Treatment Group - Treatment Arms 2C-H (Two Vaccinations)

Analysis Populations	Reason Subjects Excluded	Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
		%	n	%	n	%	n	%	n	%	n	%	n	%	n
Safety	Did not receive one dose of the vaccine	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Modified Intent-To-Treat	Any Reason														
	Did not contribute a pre-vaccination blood sample for which valid immunogenicity results were reported														
	Did not contribute at least one post-vaccination blood sample for which valid immunogenicity results were reported														
Per Protocol	**Any Timepoint**														
	Found to be ineligible at baseline[a]														
	Protocol deviation considered to affect the science[b]														
	Visit occurred substantially out of window[c]														
	Prior to or at Day 1 visit (visit 01):														
	Found to be ineligible at baseline[a]														
	Protocol deviation considered to affect the science[b]														
	Visit occurred substantially out of window[c]														
	Repeat Day 1 for:														
	Prior to or at Day 15 visit (visit 03):														
	Prior to or at Day 29 visit (visit 04):														
	Prior to or at Day 43 visit (visit 06):														

Analysis Populations	Reason Subjects Excluded	Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
		%	n	%	n	%	n	%	n	%	n	%	n	%	n
	Prior to or at Day 57 visit (visit 07):														
	Prior to or at Day 91 visit (visit 09):														
	Prior to or at Day 209 visit (visit 10):														
	Prior to or at Day 394 visit (visit 11):														

Notes: N=Number of subjects enrolled.
n=Number of subjects meeting the criteria.

Subjects may be excluded from an analysis population for multiple reasons.

[a] Subject data from all visits are excluded from the per protocol analyses. All instances of exclusion are summarized in this table.

[b] Subject data are excluded from the per protocol analyses at all timepoints subsequent to the occurrence of this protocol deviation. All instances of exclusion are summarized in this table. Subject data collected up to the time the exclusionary criterion is met is eligible for analysis.

[c] Only data from the out of window visit are excluded from the per protocol analyses.

Table 11: Ineligibility Summary of Screen Failures

Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	n[a]	%[b]
Inclusion and Exclusion	Number of subjects failing any eligibility criterion	x	100
Inclusion	Any inclusion criterion	x	xx
	[inclusion criterion 1]	x	xx
	[inclusion criterion 2]	x	xx
	[inclusion criterion 3]	x	xx
Exclusion	Any exclusion criterion	x	xx
	[exclusion criterion 1]	x	xx
	[exclusion criterion 2]	x	xx
	[exclusion criterion 3]	x	xx

[a] More than one criterion may be marked per subject.
[b] Denominator for percentages is the total number of screen failures.

14.1.2 Demographic Data by Treatment Group

Table 12: Summary of Categorical Demographic and Baseline Characteristics by Treatment Group

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Demographic Category	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Sex	Male																		
	Female																		
Ethnicity	Not Hispanic or Latino																		
	Hispanic or Latino																		
	Not Reported																		
	Unknown																		
Race	American Indian or Alaska Native																		
	Asian																		
	Native Hawaiian or other Pacific Islander																		
	Black																		
	White																		
	Multi Racial																		
	Unknown																		
Baseline N-antibody status	Negative																		
	Positive																		

Table 13: Summary of Continuous Demographic and Baseline Characteristics by Treatment Group

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Age (Years)	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Height (cm)	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Weight (kg)	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
BMI (kg/m^2)	Mean									
	Standard Deviation									
	Median									
	Minimum									

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Maximum									
Note: N=Number of subjects in the Safety Population										

14.1.3 Prior and Concurrent Medical Conditions

Table 14: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group

MedDRA System Organ Class	Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[SOC 1]																		
[SOC 2]																		
Note: N = Number of subjects in the Safety Population; n = Number of subjects reporting medical history within the specified SOC. A subject is only counted once per SOC.																		

14.2 Immunogenicity Data

Table 15: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects
Day 1, Pre-Dose	n			
	GM			
	95% CI			
Day 15	n			
	GM			
	95% CI			
Day 29	n			
	GM			
	95% CI			
Day 43	n			
	GM			
	95% CI			
Day 57	n			
	GM			
	95% CI			
Day 71	n			
	GM			
	95% CI			
Day 85	n			
	GM			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects
	95% CI			
Day 147	n			
	GM			
	95% CI			
Day 237	n			
	GM			
	95% CI			
Day 422	n			
	GM			
	95% CI			
Peak GM	n			
	GM			
	95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

Implementation notes:

For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

For all AUC tables, add footnote reading: "Geometric Mean is calculated as the Williams mean using log(1+x)."

Table 39: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n							
	GM							
	95% CI							
Day 15	n							
	GM							
	95% CI							
Day 29	n							
	GM							
	95% CI							
Day 43	n							
	GM							
	95% CI							
Day 57	n							
	GM							
	95% CI							
Day 119	n							
	GM							
	95% CI							
Day 209	n							
	GM							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	95% CI							
Day 394	n							
	GM							
	95% CI							
Peak GM	n							
	GM							
	95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

[Implementation notes: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population." For all AUC tables, add footnote reading: "Geometric Mean is calculated as the Williams mean using log(1+x)."]

Table 40: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 41: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 42: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 43: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 44: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 45: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 46: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P– B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 47: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 48: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD– B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 49: Serum IgG Binding Assay Binding Antibody Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 63: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects
Day 1, Pre-Dose	n			
	GM			
	95% CI			
Day 15	n			
	GM			
	95% CI			
Day 29	n			
	GM			
	95% CI			
Day 43	n			
	GM			
	95% CI			
Day 57	n			
	GM			
	95% CI			
Day 71	n			
	GM			
	95% CI			
Day 85	n			
	GM			
	95% CI			
Day 147	n			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects
	GM			
	95% CI			
Day 237	n			
	GM			
	95% CI			
Day 422	n			
	GM			
	95% CI			
Peak GM	n			
	GM			
	95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

[Implementation note: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."]

Table 64: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 65: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 66: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 67: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 87: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n							
	GM							
	95% CI							
Day 15	n							
	GM							
	95% CI							
Day 29	n							
	GM							
	95% CI							
Day 43	n							
	GM							
	95% CI							
Day 57	n							
	GM							
	95% CI							
Day 119	n							
	GM							
	95% CI							
Day 209	n							
	GM							
	95% CI							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 394	n							
	GM							
	95% CI							
Peak GM	n							
	GM							
	95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

[Implementation note: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."]

Table 88: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 89: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 90: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 91: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 92: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 93: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 94: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 95: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 96: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 97: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 98: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 99: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, P.1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 100: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, P.1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 111: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n			
	GM			
	95% CI			
Day 15	n			
	GM			
	95% CI			
Day 29	n			
	GM			
	95% CI			
Day 43	n			
	GM			
	95% CI			
Day 57	n			
	GM			
	95% CI			
Day 71	n			
	GM			
	95% CI			
Day 85	n			
	GM			
	95% CI			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 147	n			
	GM			
	95% CI			
Day 237	n			
	GM			
	95% CI			
Day 422	n			
	GM			
	95% CI			
Peak GM	n			
	GM			
	95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

[Implementation note: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."]

Table 112: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 113: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 114: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 115: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 116: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 117: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 118: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 119: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 120: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 121: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 122: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 123: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, P.1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 147: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n							
	GM							
	95% CI							
Day 15	n							
	GM							
	95% CI							
Day 29	n							
	GM							
	95% CI							
Day 43	n							
	GM							
	95% CI							
Day 57	n							
	GM							
	95% CI							
Day 119	n							
	GM							
	95% CI							
Day 209	n							
	GM							
	95% CI							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 395	n							
	GM							
	95% CI							
Peak GM	n							
	GM							
	95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GM=Geometric Mean, NE=Not Estimable.
Confidence intervals of the geometric means were calculated with the Student's t distribution on log-transformed data.

Tables with Similar Format:

[Implementation note: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."]

Table 148: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 149: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 150: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 151: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 152: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 153: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 154: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 155: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 156: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 157: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 158: Focus Reduction Neutralization Test ID_{80} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.617.2 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 159: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, P.1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 160: Focus Reduction Neutralization Test ID_{50} Geometric Mean Results with 95% Confidence Intervals by Time Point and Treatment Group, P.1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 183: Percentages of CD4 T Cells Expressing Cytokines with 95% CI – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 1, Pre- Dose	**Beta Mutations**	**154**	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
			95% CI[b]			
		IFNγ or IL-2/CM	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2/EM	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2/N	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		IFNγ or IL-2/TD	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 and 154	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 or 154	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 or 154/C	n			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 or 154/E	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 or 154/N	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2 or 154/T	n			
			Minimum			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IL-17a	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IL-2	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IL-4 and 154	n			
			Minimum			
			Median			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IL-4 IL-5 IL-13 and 154	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IL-5 or IL-13 and 154	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		TNFα	n			
			Minimum			
			Median			
			Maximum			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
	Repeat for all peptide pools: Beta S, Conserved S1, Conserved S2, Original Matched, Original S					
Repeat for all study days						

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Table with Similar Format:

Table 184: Percentages of CD4 T Cells Expressing Cytokines with 95% CI – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 185: Percentages of CD4 T Cells Expressing Cytokines with 95% CI – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	Beta Mutations	154	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
			95% CI[b]							
		IFNγ or IL-2/CM	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2/EM	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2/N	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		IFNγ or IL-2/TD	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2 and 154	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2 or 154	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
			n							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		IFNγ or IL-2 or 154/CM	Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2 or 154/EM	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2 or 154/N	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2 or 154/TD	n							
			Minimum							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IL-17a	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IL-2	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IL-4 and 154	n							
			Minimum							
			Median							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IL-4 IL-5 IL-13 and 154	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IL-5 or IL-13 and 154	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		TNFα	n							
			Minimum							
			Median							
			Maximum							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
	Repeat for all peptide pools: Beta S, Conserved S1, Conserved S2, Original Matched, Original S									
Repeat for all Study Days										

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Table with Similar Format:

Table 186: Percentages of CD4 T Cells Expressing Cytokines with 95% CI – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 187: Percentages of CD8 T Cells Expressing Cytokines with 95% CI – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 1, Pre- Dose	**Beta Mutations**	**IFNγ or IL-2**	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2CM	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2EM	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		IFNγ or IL-2/N	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
		IFNγ or IL-2/TD	n			
			Minimum			
			Median			
			Maximum			
			Mean			
			95% CI[a]			
			Response Rate			
			95% CI[b]			
	Repeat for all peptide pools: Beta S, Conserved S1, Conserved S2, Original Matched, Original S					
Repeat for all study days						

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Table with Similar Format:

Table 188: Percentages of CD8 T Cells Expressing Cytokines with 95% CI – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 189: Percentages of CD8 T Cells Expressing Cytokines with 95% CI – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre- Dose	**Beta Mutations**	**IFNγ or IL-2**	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2CM	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2EM	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							

Time Point	Peptide Pool	Cytokine	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2/N	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
		IFNγ or IL-2/TD	n							
			Minimum							
			Median							
			Maximum							
			Mean							
			95% CI[a]							
			Response Rate							
			95% CI[b]							
	Repeat for all peptide pools: Beta S, Conserved S1, Conserved S2, Original Matched, Original S									
Repeat for all study days										

Note: N=Number of Subjects.
n=Number of subjects with results available at time point.
NE=Not Estimable
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Table with Similar Format:

Table 190: Percentages of CD8 T Cells Expressing Cytokines with 95% CI – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 191: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 15	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 29	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 43	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 57	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 71	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 85	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 147	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 237	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 422	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

[Implementation notes: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

For all AUC tables, add footnote reading: "AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations."]

Table 192: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 193: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 194: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 195: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 196: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 197: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 198: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P– B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 199: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 215: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 15	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 29	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 43	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 57	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 119	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 209	n							
	GMFR (95% CI)[a]							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Seropositive - % (95% CI)[b]							
Day 394	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

[Implementation notes: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

For all AUC tables, add footnote reading: "AUC results reported as 0 were imputed to the lowest non-zero reported value for the purposes of fold-rise calculations."]

Table 216: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 217: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 218: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIA Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 219: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 220: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–Wa-1 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 221: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P–B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 222: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, S-2P– B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 223: Serum IgG Binding Assay Arbitrary Units/mL Measured by ECLIAv2 (4-plex) Geometric Mean Fold Rise and 4-Fold Rise Results with 95% Confidence Intervals by Time Point and Treatment Group, RBD–B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 239: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 15	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 29	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 43	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 57	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 71	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 85	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 147	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 237	n			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 422	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

Implementation notes:

For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

Table 240: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 241: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 242: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 243: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 244: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 245: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 263: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 15	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 29	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 43	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 57	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 119	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 209	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 394	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

Implementation notes:

For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

Table 264: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 265: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 266: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 267: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 268: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 287: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 15	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 29	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 43	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 57	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 71	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 85	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 147	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 237	n			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			
Day 422	n			
	GMFR (95% CI)[a]			
	Seropositive - % (95% CI)[b]			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

[Implementation notes: For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."]

Table 288: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 289: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 290: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 291: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 292: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 293: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 294: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 323: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 15	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 29	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 43	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 57	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 119	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							
Day 209	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 394	n							
	GMFR (95% CI)[a]							
	Seropositive - % (95% CI)[b]							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMFR=Geometric Mean Fold Rise, NE=Not Estimable.
[a] Confidence interval calculated based on the Student's t-distribution
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with Similar Format:

Implementation notes:

For tables using the PP population, update footnote to read: "Notes: N=Number of subjects in the Per Protocol population."

Table 324: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 325: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 326: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, D614G – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 327: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 328: Focus Reduction Neutralization Test ID_{50} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 329: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals by Time Point and Treatment Group, B.1.351 – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 330: Focus Reduction Neutralization Test ID_{80} Geometric Mean Fold Rise and Seropositivity Results with 95% Confidence Intervals

Table 359: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
B.1.617.2	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
P.1	**Day 1, Pre- Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
B.1.1.7	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
B.1.1.529	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with Similar Format:

Table 360: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 361: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 362: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 363: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Day 394	n							
		GMR							
		95% CI							
B.1.617.2	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		95% CI							
	Day 394	n							
		GMR							
		95% CI							
P.1	**Day 1, Pre- Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
	Day 394	n							
		GMR							
		95% CI							
B.1.1.7	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day119	n							
		GMR							
		95% CI							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							
		GMR							
		95% CI							
B.1.1.529	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							
		GMR							
		95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with Similar Format:

Table 364: Pseudovirus Neutralization Assay ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 365: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 366: Pseudovirus Neutralization Assay ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 367: Focus Reduction Neutralization Test ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
B.1.617.2	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
P.1	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
B.1.1.7	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
B.1.1.529	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with Similar Format:

Table 368: Focus Reduction Neutralization Test ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 369: Focus Reduction Neutralization Test ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 370: Focus Reduction Neutralization Test ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 371: Focus Reduction Neutralization Test (TMPRS cells) ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			
B.1.617.2	**Day 1, Pre-Dose**	n			
		GMR			
		95% CI			
	Day 15	n			
		GMR			
		95% CI			
	Day 29	n			
		GMR			
		95% CI			
	Day 43	n			
		GMR			
		95% CI			
	Day 57	n			
		GMR			
		95% CI			
	Day 71	n			

Variant	Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
		GMR			
		95% CI			
	Day 85	n			
		GMR			
		95% CI			
	Day 147	n			
		GMR			
		95% CI			
	Day 237	n			
		GMR			
		95% CI			
	Day 422	n			
		GMR			
		95% CI			

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with Similar Format:

Table 372: Focus Reduction Neutralization Test (TMPRS cells) ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 373: Focus Reduction Neutralization Test (TMPRS cells) ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Table 374: Focus Reduction Neutralization Test (TMPRS cells) ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 375: Focus Reduction Neutralization Test ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
B.1.617.2	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
P.1	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
B.1.1.7	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
B.1.1.529	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with Similar Format:

Table 376: Focus Reduction Neutralization Test ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 377: Focus Reduction Neutralization Test ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 378: Focus Reduction Neutralization Test ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 379: Focus Reduction Neutralization Test (TMPRS cells) ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
B.1.351	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							
B.1.1.529	**Day 1, Pre-Dose**	n							
		GMR							
		95% CI							
	Day 15	n							
		GMR							
		95% CI							
	Day 29	n							
		GMR							
		95% CI							
	Day 43	n							
		GMR							
		95% CI							
	Day 57	n							
		GMR							
		95% CI							
	Day 119	n							
		GMR							
		95% CI							
	Day 209	n							
		GMR							
		95% CI							
	Day 394	n							

Variant	Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
		GMR							
		95% CI							

Notes: N=Number of subjects in the mITT population.
n=Number of subjects with results available at time point.
GMR=Geometric Mean Ratio, NE=Not Estimable.
Geometric Mean Ratio was calculated by taking the ratio of the result for each variant divided by the result of the D614G variant for each subject and calculating the geometric mean.
Confidence interval calculated based on the Student's t-distribution

Tables with similar format:

Table 380: Focus Reduction Neutralization Test (TMPRS cells) ID_{50} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 381: Focus Reduction Neutralization Test (TMPRS cells) ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Table 382: Focus Reduction Neutralization Test (TMPRS cells) ID_{80} Geometric Mean Ratio to D614G Variant with 95% Confidence Intervals by Variant, Time Point, and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Table 383: Summary of N-Antibody Expression and Self-Reported Infection Status by Time Point and Treatment Group – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 15	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 29	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 43	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 57	n			
	% Positive			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
	95% CI			
	% Reported Infection			
	95% CI			
Day 71	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 85	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 147	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 237	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Day 422	n			

Planned Time Point	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	All Subjects (N=X)
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			
Any Time Point	n			
	% Positive			
	95% CI			
	% Reported Infection			
	95% CI			

Notes: n=number of subjects with results available at time point.
Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Table with Similar Format:

Table 384: Summary of N-Antibody Expression and Self-Reported Infection Status by Time Point and Treatment Group – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Table 385: Summary of N-Antibody Expression and Self-Reported Infection Status by Time Point and Treatment Group – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Day 1, Pre-Dose	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 15	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 29	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 43	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 57	n							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 119	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 209	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Day 394	n							
	% Positive							
	95% CI							
	% Reported Infection							
	95% CI							
Any Time Point	n							
	% Positive							
	95% CI							

Planned Time Point	Statistic	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	% Reported Infection							
	95% CI							
Notes: n=number of subjects with results available at time point. Exact binomial confidence interval calculated using the Clopper-Pearson methodology.								

Table with Similar Format:

Table 386: Summary of N-Antibody Expression and Self-Reported Infection Status by Time Point and Treatment Group – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

14.3 Safety Data

14.3.1 Displays of Adverse Events

Table 387: Overall Summary of Adverse Events by Treatment Group - All Subjects

Subjects[a] with		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Category 1	**Category 2**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	%	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one local solicited adverse event	NA																		
At least one systemic solicited adverse event	NA																		
At least one unsolicited adverse event	NA																		
At least one related unsolicited adverse event	Any Grade																		
	Mild (Grade 1)																		
	Moderate (Grade 2)																		
	Severe (Grade 3)																		
At least one severe (Grade 3) unsolicited adverse event	Any relationship																		
	Related																		
	Unrelated																		
At least one serious adverse event[b]	Any relationship																		

Subjects[a] with		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Category 1	**Category 2**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	%	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Related																		
	Unrelated																		
At least one adverse event leading to early termination[c]	N/A																		
Any Vital Signs Adverse Event	N/A																		
At least one medically attended adverse event	N/A																		
At least one new onset chronic medical condition	N/A																		

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 157.
[c]As reported on the Adverse Event eCRF.

Table 388: Serious Adverse Events and Non-Serious Adverse Events Occurring in 5% of Subjects in Any Treatment Group by MedDRA System Organ Class and Preferred Term, and Treatment Group - All Subjects

Preferred Term	MedDRA System Organ Class	Arm 2A (N=X)			Arm 2B (N=X)			Arm 2C (N=X)			Arm 2D (N=X)			Arm 2E (N=X)			Arm 2F (N=X)			Arm 2G (N=X)			Arm 2H (N=X)			All Subjects (N=X)		
		n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events
Serious Adverse Events																												
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc.	Etc.																											
Other (Non-serious) Adverse Events																												
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc	Etc																											

N = number of subjects in the Safety Population (number of subjects at risk).
n= number of subjects reporting event.
Events= total frequency of events reported.

14.3.1.1 Solicited Adverse Events

Table 389: Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, and Treatment Group

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Symptom	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Any Systemic Symptom	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Arthralgia	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Fatigue	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Fever[a]	**None**																		
	Mild																		
	Moderate																		
	Severe																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Feverishness	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Headache	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Myalgia	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Nausea	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Any Local Symptom	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Erythema/Redness	**None**																		
	Mild																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Moderate																		
	Severe																		
Erythema/Redness Measurement (mm)	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Induration/Swelling	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Induration/Swelling Measurement (mm)	**None**																		
	Mild																		
	Moderate																		
	Severe																		
Pain	**None**																		
	Mild																		
	Moderate																		
	Severe																		

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

Table 390: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2A (Three Vaccinations)

		Pre-Dose (N=X)		Post-Dose (N=X)		Day 1 (N=X)		Day 2 (N=X)		Day 3 (N=X)		Day 4 (N=X)		Day 5 (N=X)		Day 6 (N=X)		Day 7 (N=X)		Day 8+ [1] (N=X)		Any Post-Dose[2]	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Symptom	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Any Systemic Symptom	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Arthralgia	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Fatigue	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Fever	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Feverishness	**None**																						
	Mild																						

		Pre-Dose (N=X)		Post-Dose (N=X)		Day 1 (N=X)		Day 2 (N=X)		Day 3 (N=X)		Day 4 (N=X)		Day 5 (N=X)		Day 6 (N=X)		Day 7 (N=X)		Day 8+ [1] (N=X)		Any Post-Dose[2]	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Moderate																						
	Severe																						
Headache	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Myalgia	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Nausea	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Any Local Symptom	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Erythema/Redness	**None**																						
	Mild																						
	Moderate																						
	Severe																						
	None																						

		Pre-Dose (N=X)		Post-Dose (N=X)		Day 1 (N=X)		Day 2 (N=X)		Day 3 (N=X)		Day 4 (N=X)		Day 5 (N=X)		Day 6 (N=X)		Day 7 (N=X)		Day 8+ [1] (N=X)		Any Post-Dose[2]	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Redness Measurement (mm)	**Mild**																						
	Moderate																						
	Severe																						
Induration/Swelling	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Induration/Swelling Measurement (mm)	**None**																						
	Mild																						
	Moderate																						
	Severe																						
Pain	**None**																						
	Mild																						
	Moderate																						
	Severe																						

Notes: N=Number of subjects in the Safety Population.
Severity is the maximum severity reported post dosing for each subject for each day.
[1] Day 8+ includes the maximum severity of each symptom reported on or after Day 8 (includes ongoing symptoms)
[2] Indicates how many subjects had "None", "Mild", "Moderate", or "Severe" as their maximum severity for any day. A subject may be counted in more than one of these categories.

Tables with Similar Format:

[Implementation note: For any symptoms or days with missing data, add a "Not Reported" row.]

Table 391: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2A (Three Vaccinations)

Table 392: Summary of Solicited Events by Days Post Dose 3, Symptom, and Treatment Group – Treatment Arm 2A (Three Vaccinations)

Table 393: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2B (Three Vaccinations)

Table 394: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2B (Three Vaccinations)

Table 395: Summary of Solicited Events by Days Post Dose 3, Symptom, and Treatment Group – Treatment Arm 2B (Three Vaccinations)

Table 396: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2C (Two Vaccinations)

Table 397: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2C (Two Vaccinations)

Table 398: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2D (Two Vaccinations)

Table 399: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2D (Two Vaccinations)

Table 400: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2E (Two Vaccinations)

Table 401: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2E (Two Vaccinations)

Table 402: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2F (Two Vaccinations)

Table 403: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2F (Two Vaccinations)

Table 404: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2G (Two Vaccinations)

Table 405: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2G (Two Vaccinations)

Table 406: Summary of Solicited Events by Days Post Dose 1, Symptom, and Treatment Group – Treatment Arm 2H (Two Vaccinations)

Table 407: Summary of Solicited Events by Days Post Dose 2, Symptom, and Treatment Group – Treatment Arm 2H (Two Vaccinations)

Table 408: Summary of Number of Days of Solicited Symptoms by Treatment Group - All Subjects

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Any Symptom	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Any Systemic Symptom	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Arthralgia	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Fatigue	n									
	Mean									

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Fever	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Feverishness	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Headache	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
Myalgia	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Nausea	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Any Local Symptom	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Erythema/redness	n									
	Mean									
	Standard Deviation									
	Median									

Variable	Statistic	Arm 2A (N=X)	Arm 2B (N=X)	Arm 2C (N=X)	Arm 2D (N=X)	Arm 2E (N=X)	Arm 2F (N=X)	Arm 2G (N=X)	Arm 2H (N=X)	All Subjects (N=X)
	Minimum									
	Maximum									
Induration/swelling	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									
Pain	n									
	Mean									
	Standard Deviation									
	Median									
	Minimum									
	Maximum									

Notes: N=Number of subjects in the Safety Population.
n=Number of solicited adverse events.

14.3.1.2 Unsolicited Adverse Events

Table 409: All Adverse Events Cross-Classified by MedDRA System Organ Class, Severity, Relationship to Study Treatment, and Treatment Group

			Relationship to Vaccination		
Treatment Group	**MedDRA System Organ Class**	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Arm 2A (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2B (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2C (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2D (N=X)	Any SOC	Mild			
		Moderate			

			Relationship to Vaccination		
Treatment Group	**MedDRA System Organ Class**	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2E (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2F (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
Arm 2G (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			

			Relationship to Vaccination		
Treatment Group	**MedDRA System Organ Class**	**Severity**	**Not Related (n)**	**Related (n)**	**Not Yet Determined (n)**
Arm 2H (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			
All Subjects (N=X)	Any SOC	Mild			
		Moderate			
		Severe			
	[Repeat for all reported SOC]	Mild			
		Moderate			
		Severe			

Notes: N=Number of subjects in the Safety Population.
n=Number of events.

Table 410: Summary of All Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group

				Severity			Relationship to Study Vaccination		
Treatment Group	**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)**
Arm 2A (N=X)	Any SOC	Any PT							
	[SOC 1]	Any PT							
		[PT 1]							
		[Repeat for all reported PT]							
	[Repeat for all reported SOC]	Any PT							
		[Repeat for all reported PT]							
Arm 2B (N=X)	Any SOC	Any PT							
	[Repeat for all reported SOC]	Any PT							
		[Repeat for all reported PT]							
All Subjects (N=X)	Any SOC	Any PT							
	[Repeat for all reported SOC]	Any PT							
		[Repeat for all reported PT]							

Notes: N=Number of subjects in the Safety Population.
n=Number of events.

Table 411: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Treatment Group

					Severity						Relationship to Study Vaccination			
			Any Incidence		Mild		Moderate		Severe		Not Related		Related	
Treatment Group	MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Arm 2A (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2B (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2C (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2D (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2E (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												

					Severity						Relationship to Study Vaccination			
			Any Incidence		Mild		Moderate		Severe		Not Related		Related	
Treatment Group	**MedDRA System Organ Class**	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Arm 2F (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2G (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
Arm 2H (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												
All Subjects (N=X)	Any SOC	Any PT												
	[Repeat for all reported SOC]	Any PT												
		[Repeat for all reported PT]												

Note: N=Number of subjects in the Safety Population.
n=Number of subjects reporting event with the specified SOC.
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.

14.3.2 Listing of Deaths, Other Serious and Significant Adverse Events

Table 412: Listing of Serious Adverse Events

Adverse Event	No. of Days Post Associated Dose (Duration)	No. of Days Post Dose the Event Became Serious	Reason Reported as an SAE	Severity	Relationship to Study Treatment	If Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Treatment Group: , AE Number:											
Comments:											
Subject ID: , Treatment Group: , AE Number:											
Comments:											

Table 413: Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events

Adverse Event	No. of Days Post Vaccination (Duration)	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	Adverse Event
Treatment Group: , Dose #: :, Subject ID, AE Number:										
Comments:										
Treatment Group: , Dose #: :, Subject ID, AE Number:										
Comments:										

Table 414: Listing of AESIs, MAAEs, and NOCMCs

Subject ID	Treatment Group	Event Description	Date of Product Administration[a]	Duration of Event	Date of Onset	MedDRA® Sytem Organ Class	MAAEs	NOCMCs	Relationship[b]	Outcome

14.3.3 Narratives of Deaths, Other Serious and Significant Adverse Events

(not included in SAP, but this is a placeholder for the CSR)

14.3.6 Displays of Vital Signs

Table 415: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Any Assessment – All Subjects, Treatment Arms 2A-B (Three Vaccinations)

		Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
Time Point	Severity	n	%	n	%	n	%
Baseline	None						
	Mild						
	Moderate						
	Severe						
Day 15	None						
	Mild						
	Moderate						
	Severe						
Day 29	None						
	Mild						
	Moderate						
	Severe						
Day 43	None						
	Mild						
	Moderate						
	Severe						
Day 57	None						
	Mild						
	Moderate						
	Severe						

		Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**
Day 71	**None**						
	Mild						
	Moderate						
	Severe						
Day 85	**None**						
	Mild						
	Moderate						
	Severe						
Day 147	**None**						
	Mild						
	Moderate						
	Severe						
Day 237	**None**						
	Mild						
	Moderate						
	Severe						
Day 422	**None**						
	Mild						
	Moderate						
	Severe						
Max Severity Post Baseline	**None**						
	Mild						
	Moderate						

		Arm 2A (N=X)		Arm 2B (N=X)		All Subjects (N=X)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**
	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.

Tables with Similar Format:

Table 416: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Systolic Blood Pressure – All Subjects, Treatment Arms 2A-B (Three Vaccinations)

Table 417: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Diastolic Blood Pressure – All Subjects, Treatment Arms 2A-B (Three Vaccinations)

Table 418: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Pulse Rate – All Subjects, Treatment Arms 2A-B (Three Vaccinations)

Table 419: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Temperature – All Subjects, Treatment Arms 2A-B (Three Vaccinations)

Table 420: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Any Assessment – All Subjects, Treatment Arms 2C-H (Two Vaccinations)

		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Time Point	Severity	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Baseline	None														
	Mild														
	Moderate														
	Severe														
Day 15	None														
	Mild														
	Moderate														
	Severe														
Day 29	None														
	Mild														
	Moderate														
	Severe														
Day 43	None														
	Mild														
	Moderate														
	Severe														
Day 57	None														
	Mild														
	Moderate														
	Severe														

		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
Time Point	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Day 119	**None**														
	Mild														
	Moderate														
	Severe														
Day 209	**None**														
	Mild														
	Moderate														
	Severe														
Day 394	**None**														
	Mild														
	Moderate														
	Severe														
Max Severity Post Baseline	**None**														
	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.

Tables with Similar Format:

Table 421: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Systolic Blood Pressure – All Subjects, Treatment Arms 2C-H (Two Vaccinations)

Table 422: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Diastolic Blood Pressure – All Subjects, Treatment Arms 2C-H (Two Vaccinations)

Table 423: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Pulse Rate – All Subjects, Treatment Arms 2C-H (Two Vaccinations)

Table 424: Vital Signs by Assessment, Maximum Severity, Time Point, and Treatment Group, Temperature – All Subjects, Treatment Arms 2C-H (Two Vaccinations)

14.4 Summary of Concomitant Medications

Table 425: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group – All Subjects

[Implementation Note: Table below contains example medications.]

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Level 1 Codes	**Any Level 2 Codes**																		
Alimentary Tract And Metabolism	**Any Level 2 Codes**																		
	Antidiarrheals, Intestinal Antiinflammatory /Antiinfective Agents																		
	Antiemetics And Antinauseants																		
	Digestives, Incl. Enzymes																		
	Drugs For Acid Related Disorders																		
	Drugs For Constipation																		
	Drugs Used In Diabetes																		
	Mineral Supplements																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Other Alimentary Tract And Metabolism Products																		
	Stomatological Preparations																		
	Vitamins																		
Antiinfectives For Systemic Use	**Any Level 2 Codes**																		
	Antibacterials For Systemic Use																		
	Antimycotics For Systemic Use																		
	Antivirals For Systemic Use																		
	Vaccines																		
Antineoplastic And Immunomodulating Agents	**Any Level 2 Codes**																		
	Antineoplastic Agents																		
	Endocrine Therapy																		
Blood And Blood Forming Organs	**Any Level 2 Codes**																		
	Antianemic Preparations																		
	Antithrombotic Agents																		
	Any Level 2 Codes																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Cardiovascular System	**Agents Acting On The Renin-Angiotensin System**																		
	Beta Blocking Agents																		
	Calcium Channel Blockers																		
	Cardiac Therapy																		
	Diuretics																		
	Lipid Modifying Agents																		
	Vasoprotectives																		
Dermatologicals	**Any Level 2 Codes**																		
	Anti-Acne Preparations																		
	Antibiotics And Chemotherapeutics For Dermatological Use																		
	Antifungals For Dermatological Use																		
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Antiseptics And Disinfectants																		
	Corticosteroids, Dermatological Preparations																		
	Emollients And Protectives																		
	Other Dermatological Preparations																		
	Preparations For Treatment Of Wounds And Ulcers																		
Genito Urinary System And Sex Hormones	**Any Level 2 Codes**																		
	Gynecological Antiinfectives And Antiseptics																		
	Other Gynecologicals																		
	Sex Hormones And Modulators Of The Genital System																		
	Urologicals																		
Musculo-Skeletal System	**Any Level 2 Codes**																		
	Antiinflammatory And Antirheumatic Products																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Drugs For Treatment Of Bone Diseases																		
	Muscle Relaxants																		
	Other Drugs For Disorders Of The Musculo-Skeletal System																		
Nervous System	**Any Level 2 Codes**																		
	Analgesics																		
	Anesthetics																		
	Other Nervous System Drugs																		
	Psychoanaleptics																		
	Psycholeptics																		
Respiratory System	**Any Level 2 Codes**																		
	Antihistamines For Systemic Use																		
	Cough And Cold Preparations																		
	Drugs For Obstructive Airway Diseases																		
	Nasal Preparations																		
Sensory Organs	**Any Level 2 Codes**																		

		Arm 2A (N=X)		Arm 2B (N=X)		Arm 2C (N=X)		Arm 2D (N=X)		Arm 2E (N=X)		Arm 2F (N=X)		Arm 2G (N=X)		Arm 2H (N=X)		All Subjects (N=X)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Ophthalmologicals																		
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	**Any Level 2 Codes**																		
	Corticosteroids For Systemic Use																		
	Thyroid Therapy																		
Various	**Any Level 2 Codes**																		
	General Nutrients																		
	Unspecified Herbal And Traditional Medicine																		

Notes: N=Number of subjects in the Safety Population.
n=Number of subjects reporting taking at least one medication in the specific WHO Drug Class.

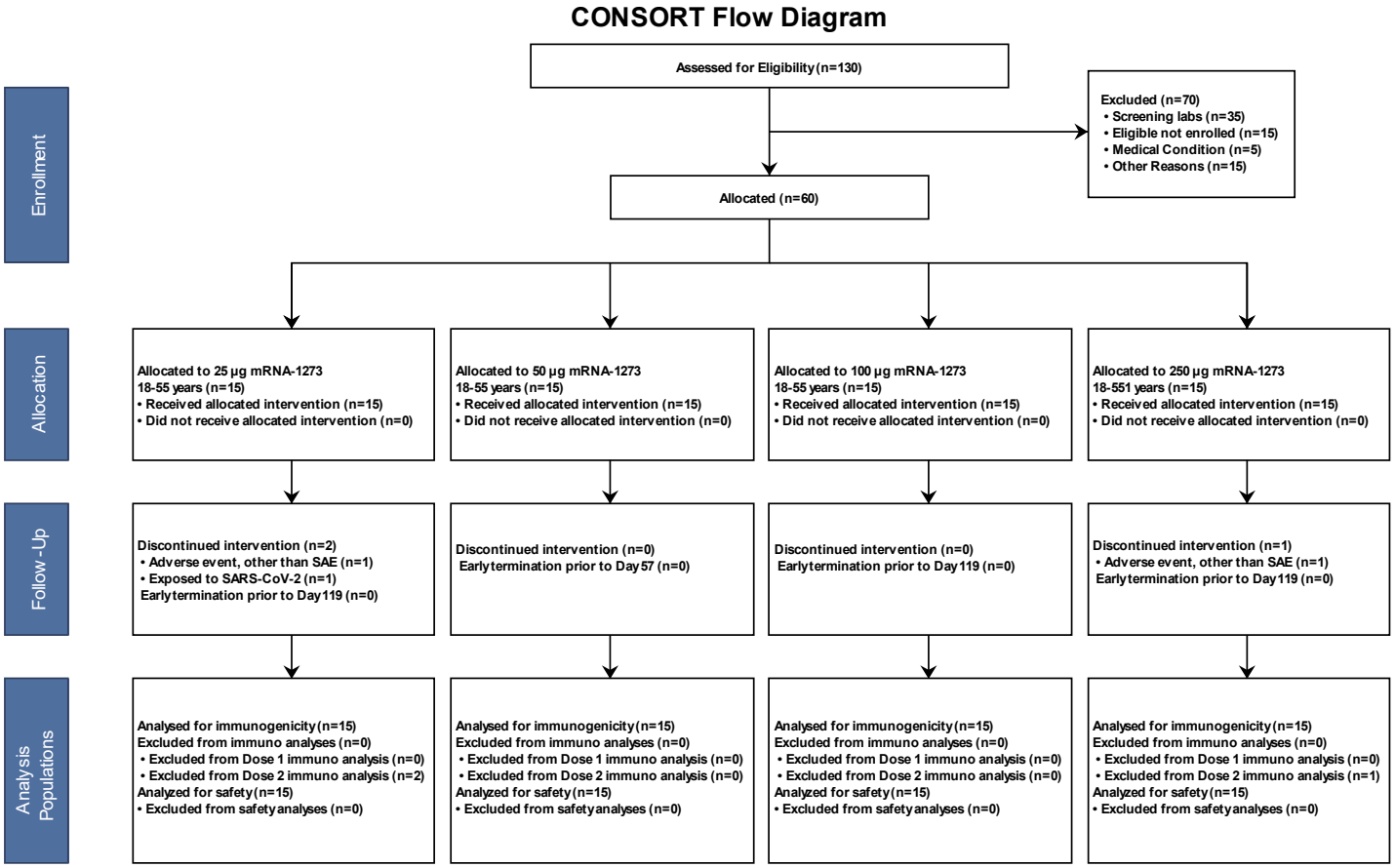
APPENDIX 2. FIGURE MOCK-UPS

LIST OF FIGURES

10.1 Disposition of Subjects

Figure 1: CONSORT Flow Diagram

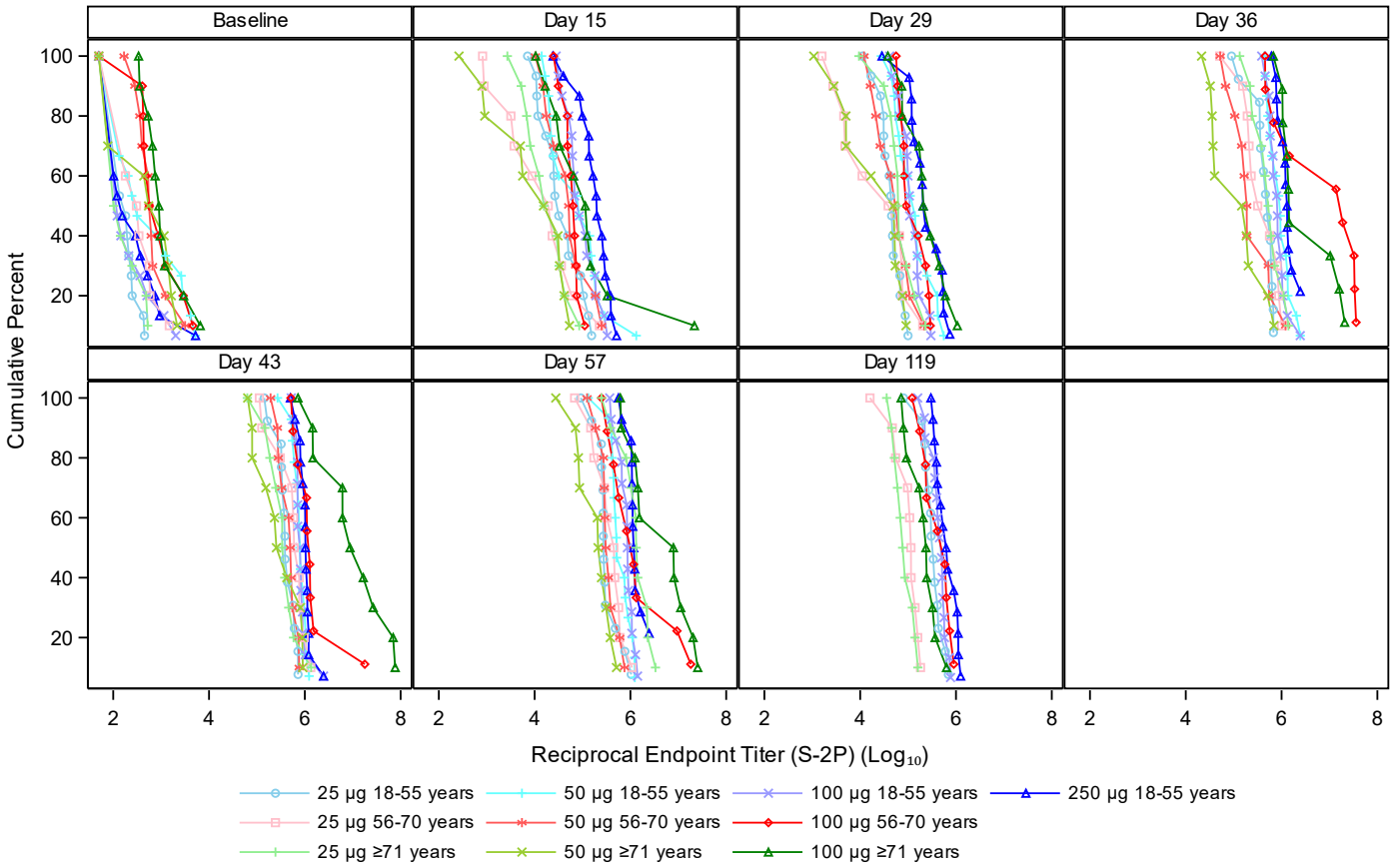
[Implementation Note: Below is an example CONSORT diagram. The final CONSORT will include Arms 2A-H.]



14.2.2 Immunogenicity Response Figures by Measure, Treatment/Vaccination, and Time Point

Figure 2: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group - S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

[Implementation Note: Below is an example figure. Lines will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422. The x-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]



Figures with Similar Format:

Figure 3: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 4: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 5: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 6: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 7: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 8: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 9: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 10: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 11: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 12: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

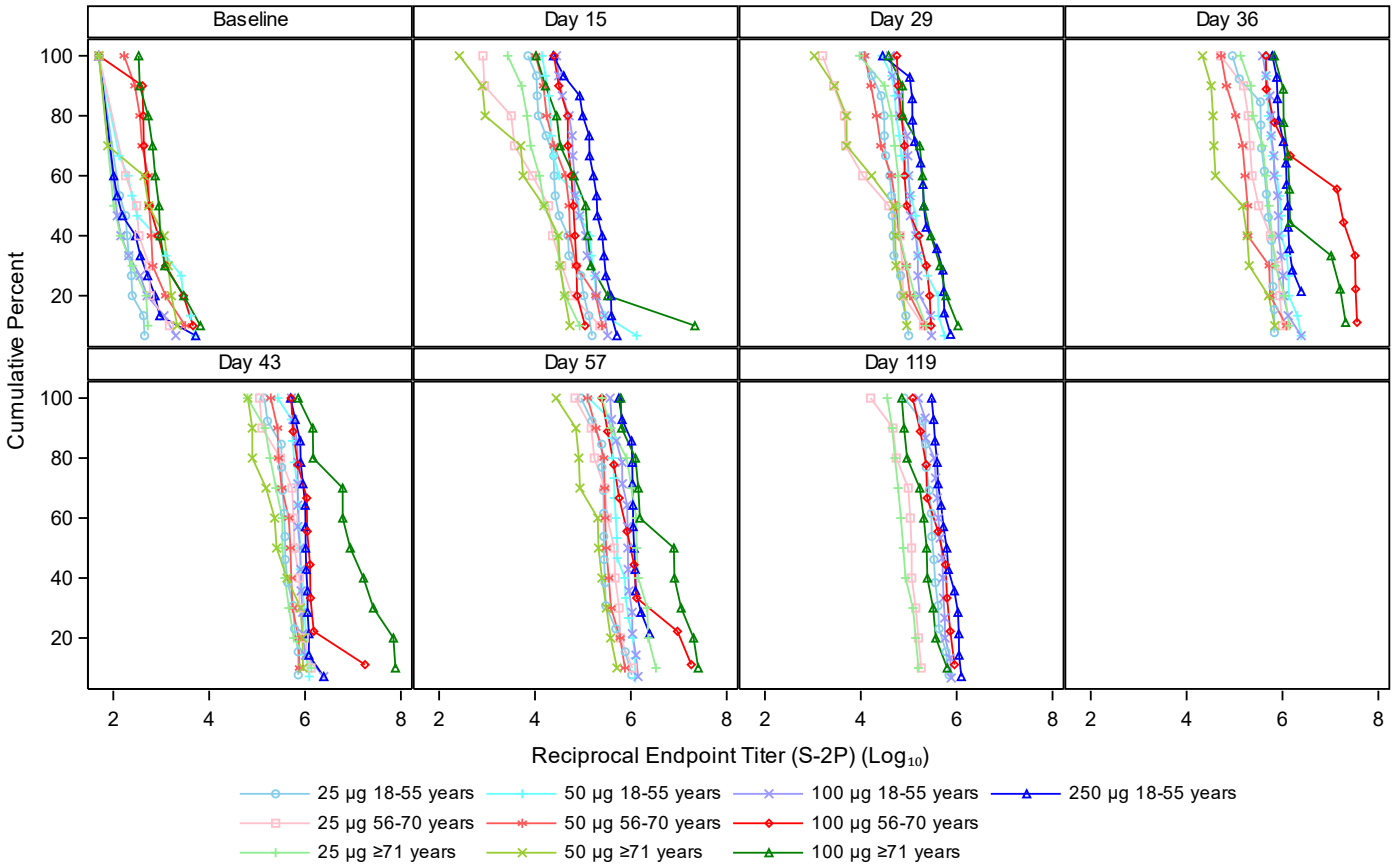
Figure 13: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 14: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 15: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 86: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group - S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation Note: Below is an example figure. Lines will only be shown for the six two-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 119, 209, and 394. The x-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]



Figures with Similar Format:

Figure 87: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 88: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 89: Reverse Cumulative Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 90: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 91: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 92: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 93: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 94: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 95: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 96: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

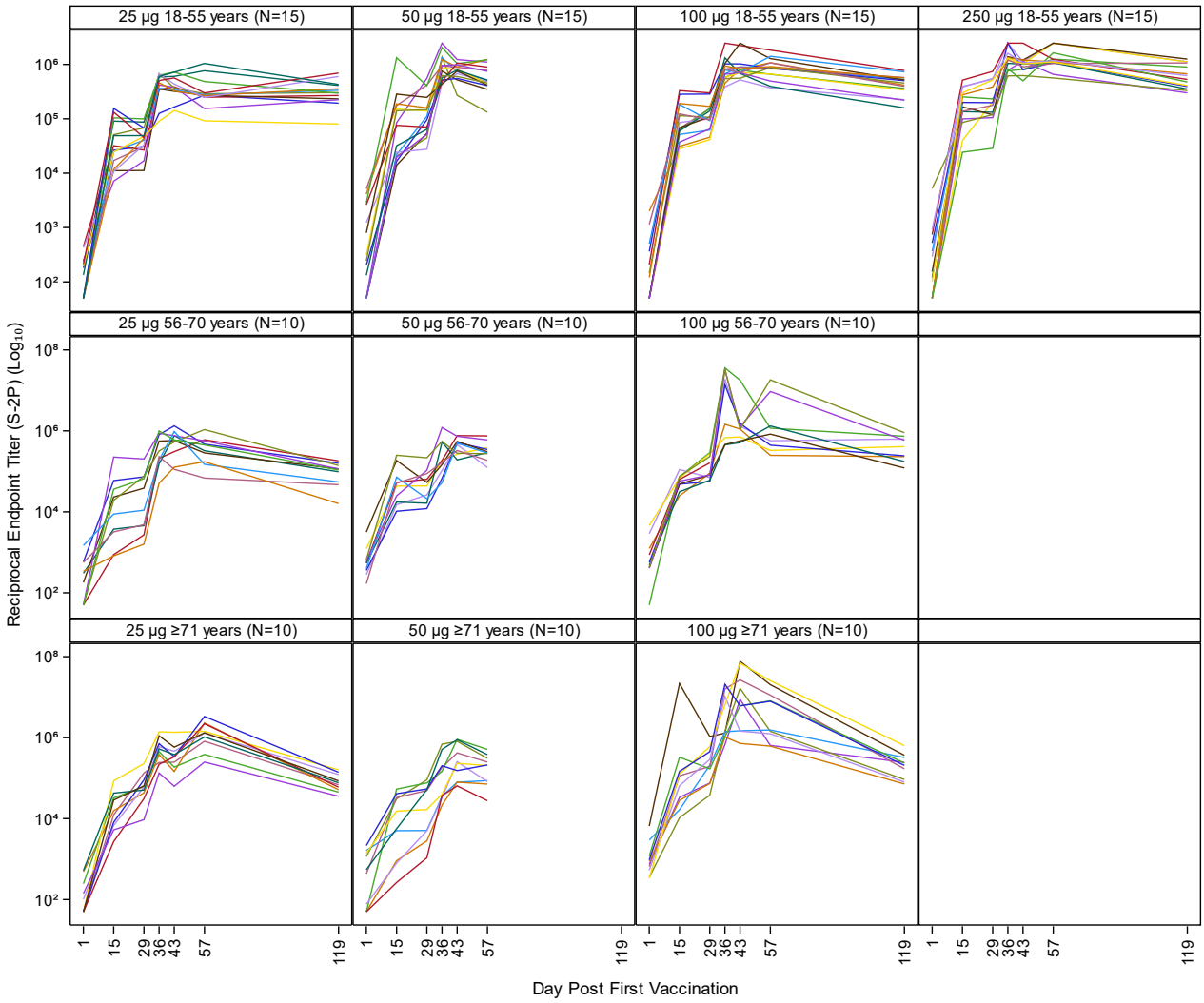
Figure 97: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 98: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 99: Reverse Cumulative Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 170: Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

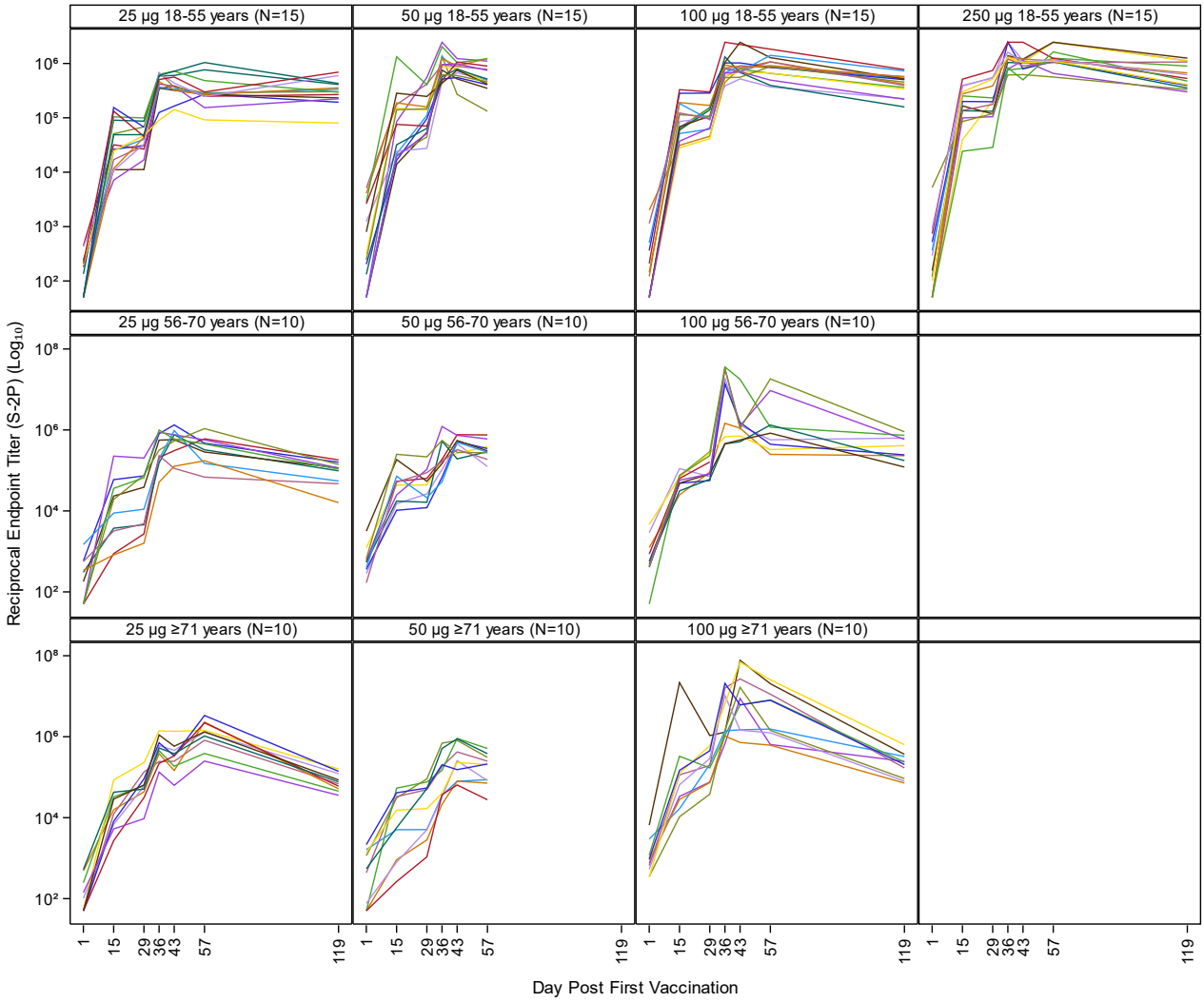
[Implementation Note: Below is an example figure. Panels will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422.The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]



Figures with Similar Format:

Figure 254: Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation Note: Below is an example figure. Panels will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 119, 209, and 394. The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]



Figures with Similar Format:

Figure 255: Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 256: Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 257: Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 258: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 259: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 260: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 261: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 262: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 263: Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 264: Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 265: Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 266: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 267: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 268: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

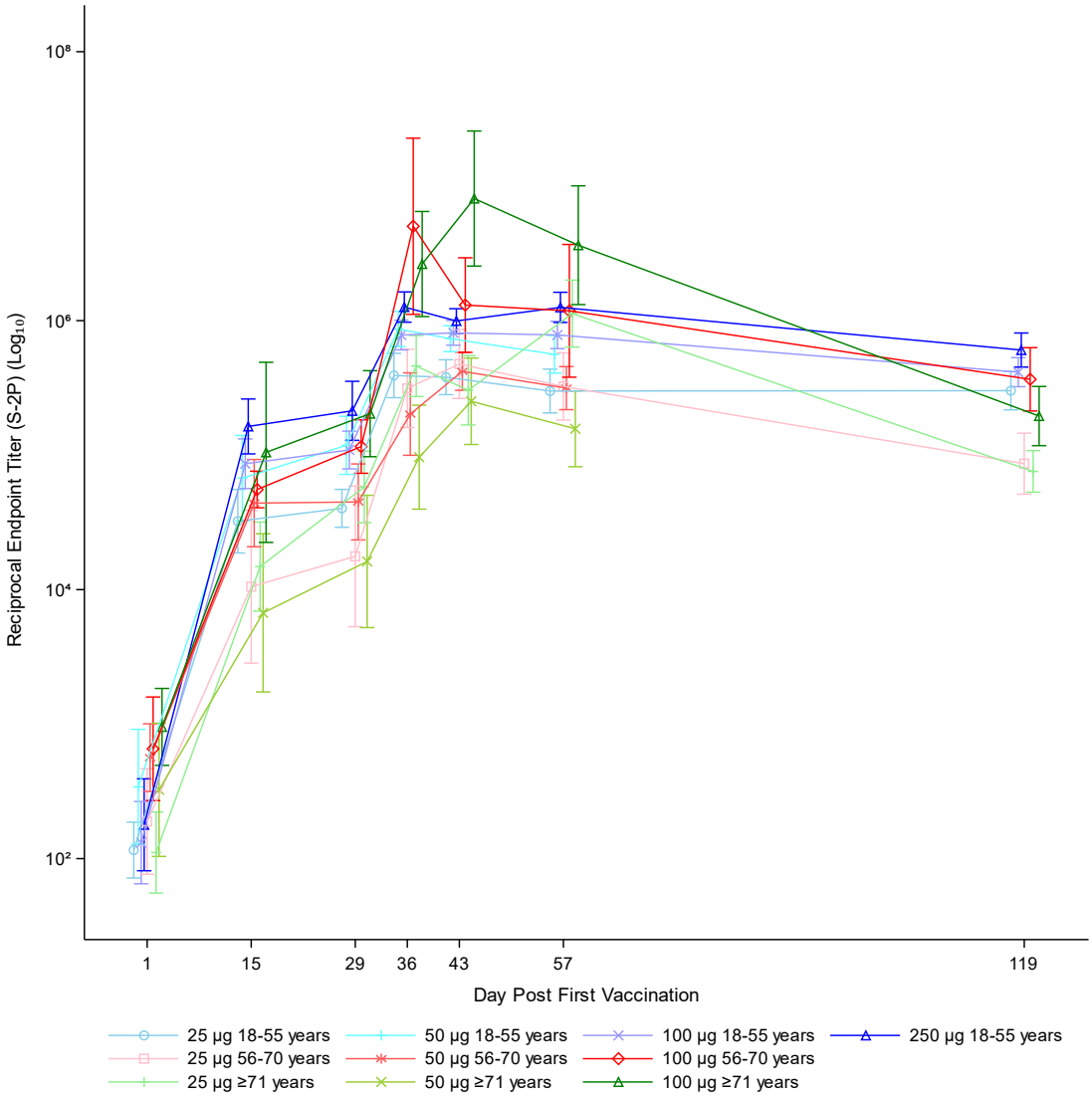
Figure 269: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 270: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P– B.1.617.2, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 271: Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P– B.1.617.2, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 338: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

[Implementation Note: Below is an example figure. Lines will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422. The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]]



Figures with Similar Format:

Figure 339: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 340: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 341: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 342: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 343: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 344: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 345: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 346: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 347: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 348: Geometric Mean Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 349: Geometric Mean Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

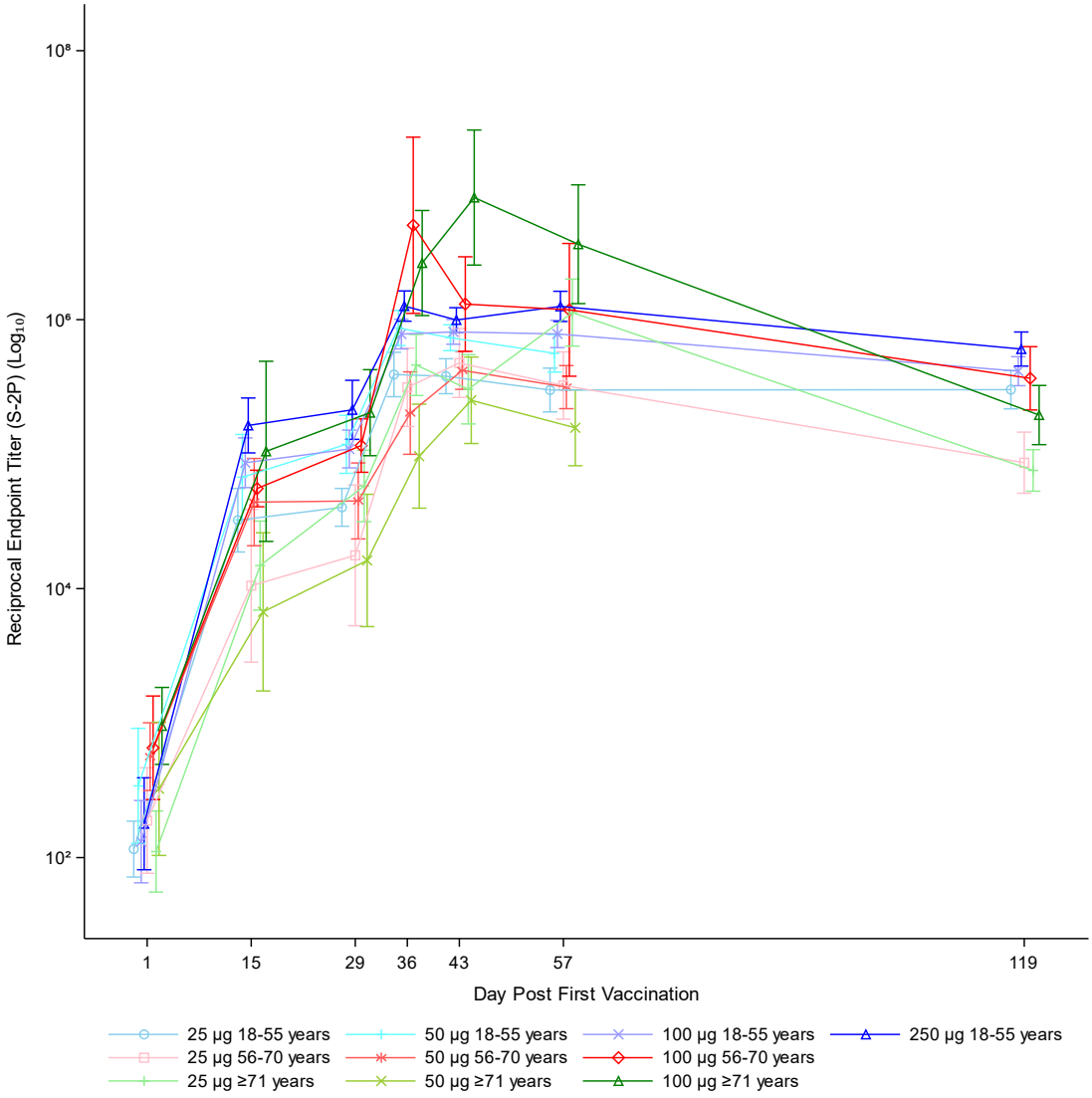
Figure 350: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 351: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 352: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point

Figure 422: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation Note: Below is an example figure. Lines will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 119, 209, and 394. The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]]



Figures with Similar Format:

Figure 423: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 424: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 425: Geometric Mean Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 426: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 427: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 428: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 429: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 430: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 431: Geometric Mean Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 432: Geometric Mean Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 433: Geometric Mean Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

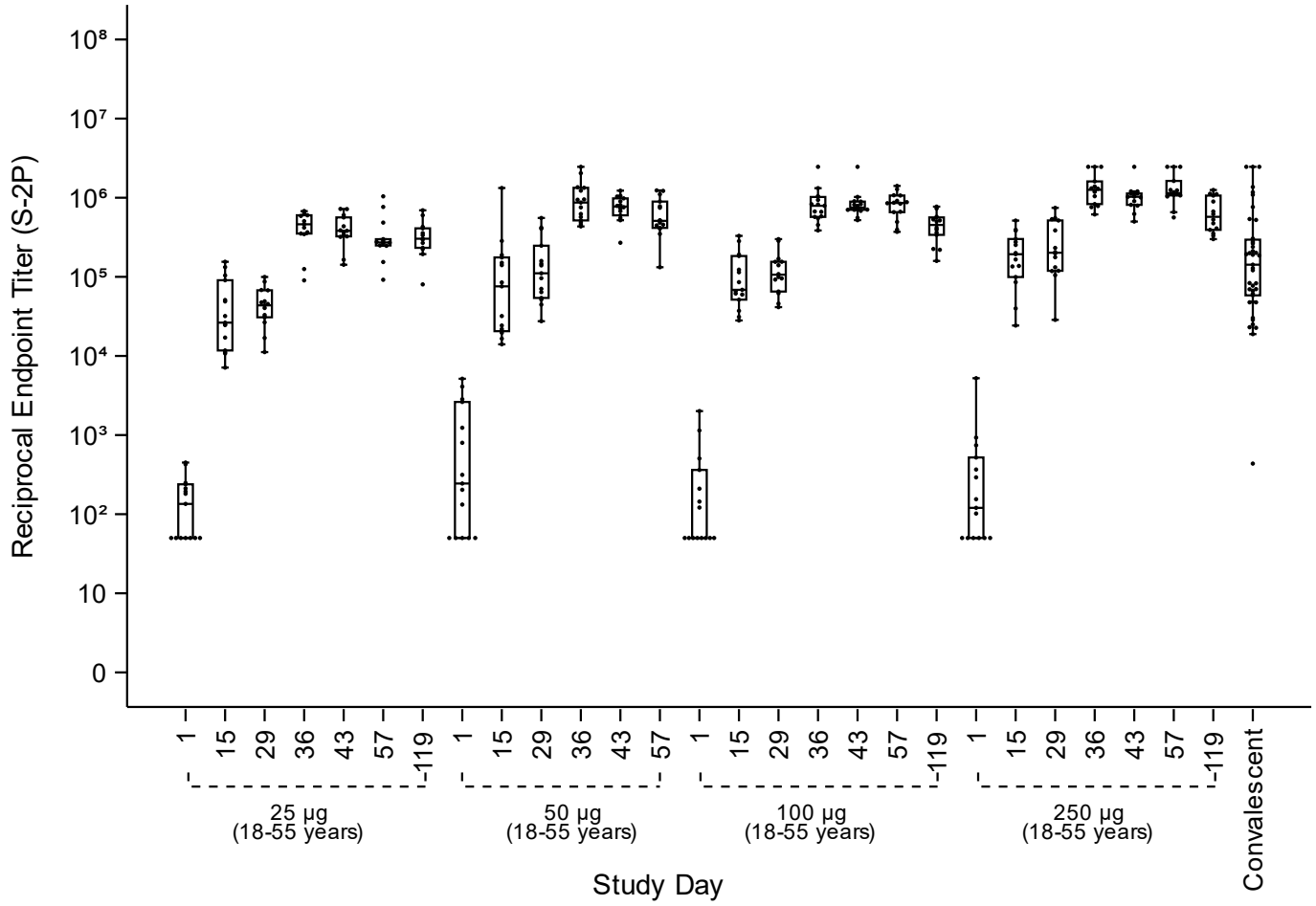
Figure 434: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 435: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 436: Geometric Mean Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point

Figure 506: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

[Implementation note: Below is an example figure. Plots will only be shown for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422 The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.].**]**



Figures with Similar Format:

Figure 507: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 508: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 509: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 510: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 511: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 512: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 513: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 514: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 515: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 516: Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

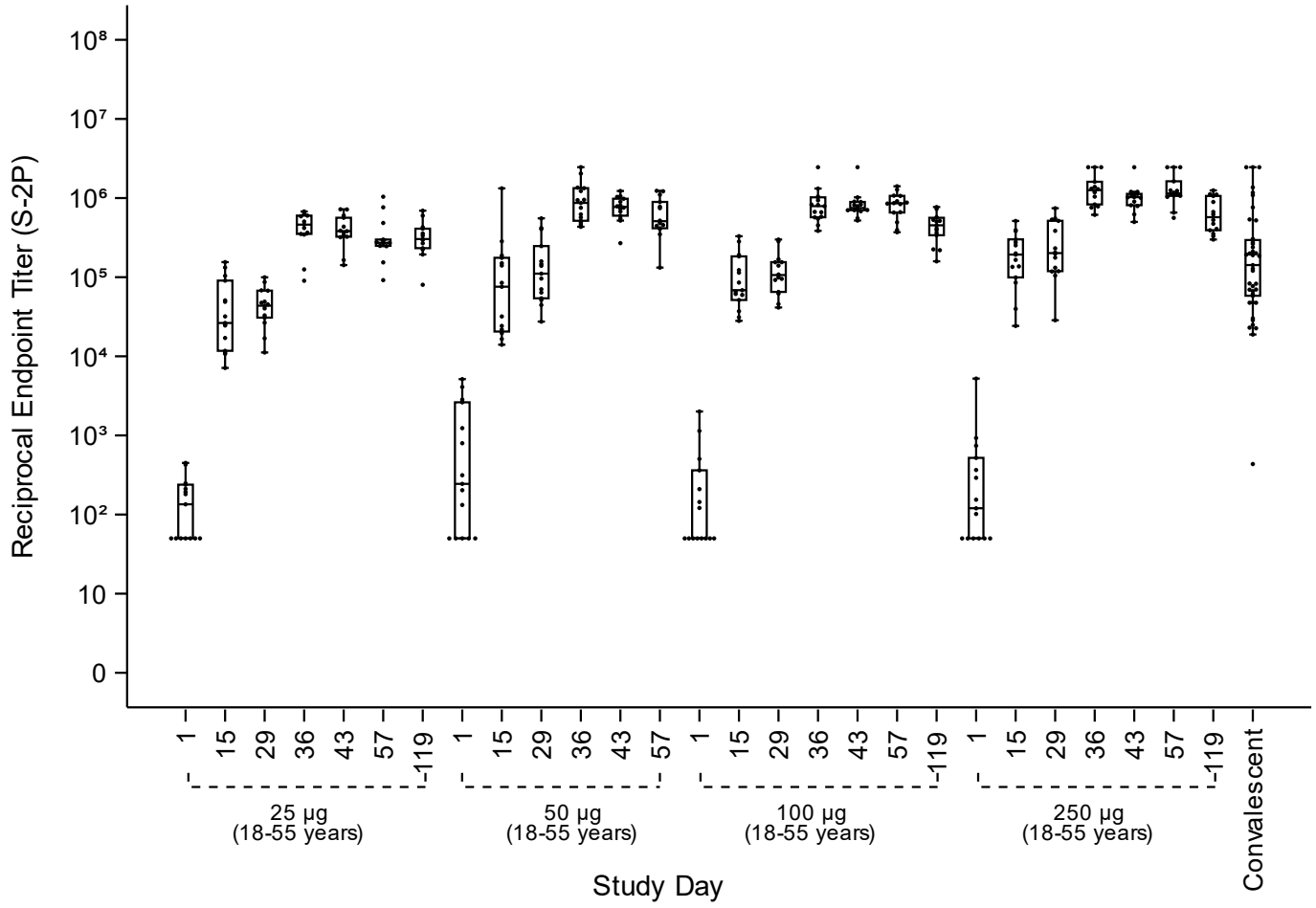
Figure 517: Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 518: Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 519: Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 590: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation note: Below is an example figure. Plots will only be shown for the six two-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 119, 209, and 394. The y-axis label should read "Arbitrary Units/mL (S-2P-Wa-1) (log_{10})." Asterisks on the Study Day labels will denote vaccination days.]**



Figures with Similar Format:

Figure 591: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 592: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 593: Distribution of Serum IgG ECLIA Arbitrary Units/mL by Time Point and Treatment Group – RBD–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 594: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 595: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 596: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 597: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – S-2P–B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 598: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 599: Distribution of Serum IgG ECLIAv2 (4-plex) Arbitrary Units/mL by Time Point and Treatment Group – RBD– B.1.351, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 600: Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

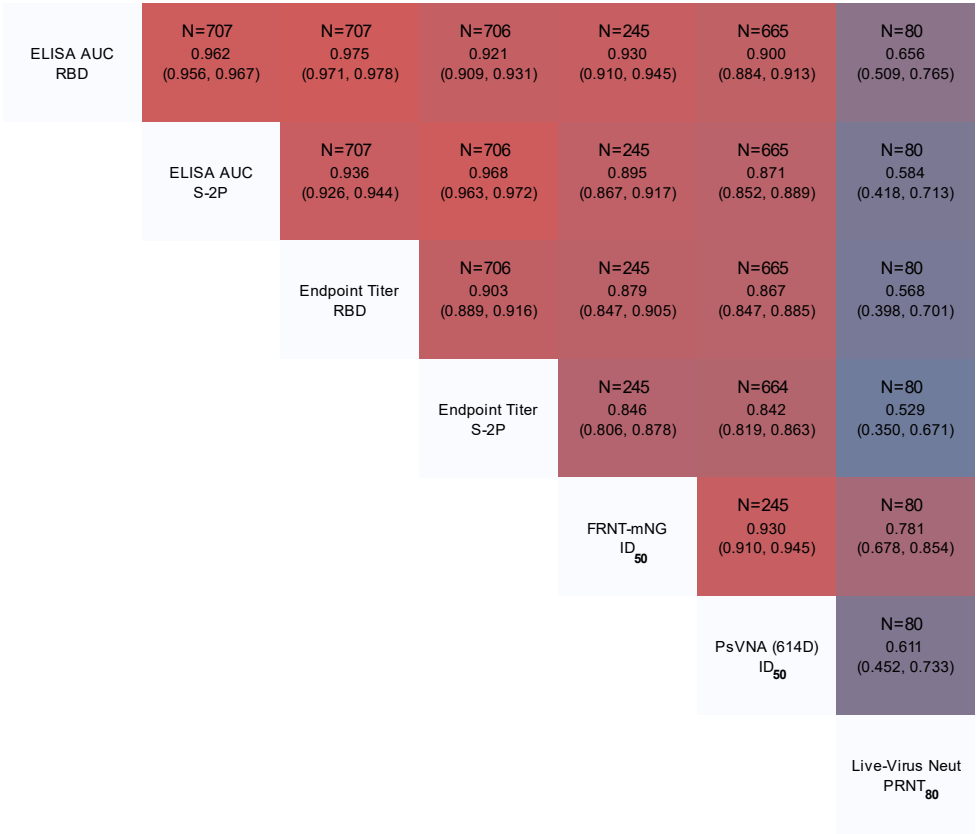
Figure 601: Distribution of Serum IgG ECLIAv2 (4-plex) Binding Antibody Units/mL by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 602: Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 603: Distribution of Serum IgG ECLIAv2 (10-plex) Area Under the Curve by Time Point and Treatment Group – S-2P–Wa-1, Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation note: Below is a sample figure. The figure will include all immunoassays which measured D614G.]

Figure 674: Correlation Heatmap, D614G – mITT Population, Treatment Arms 2A-B (Three Vaccinations)



Figures with Similar Format:

Figure 675: Correlation Heatmap, D614G – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 676: Correlation Heatmap, B.1.351 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 677: Correlation Heatmap, B.1.351 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 678: Correlation Heatmap, B.1.617.2 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 679: Correlation Heatmap, B.1.617.2 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 680: Correlation Heatmap, P.1 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 681: Correlation Heatmap, P.1 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

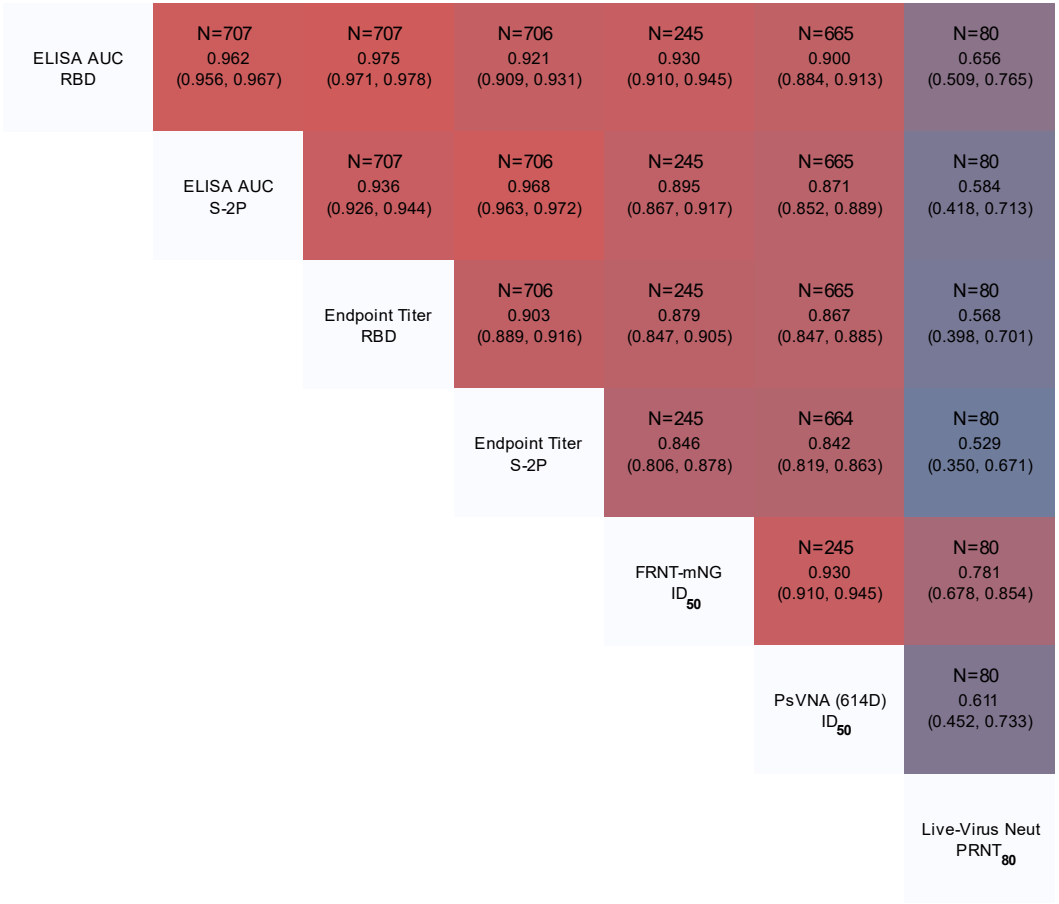
Figure 682: Correlation Heatmap, B.1.1.7 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 683: Correlation Heatmap, B.1.1.7 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 684: Correlation Heatmap, B.1.1.529 – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 685: Correlation Heatmap, B.1.1.529 – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

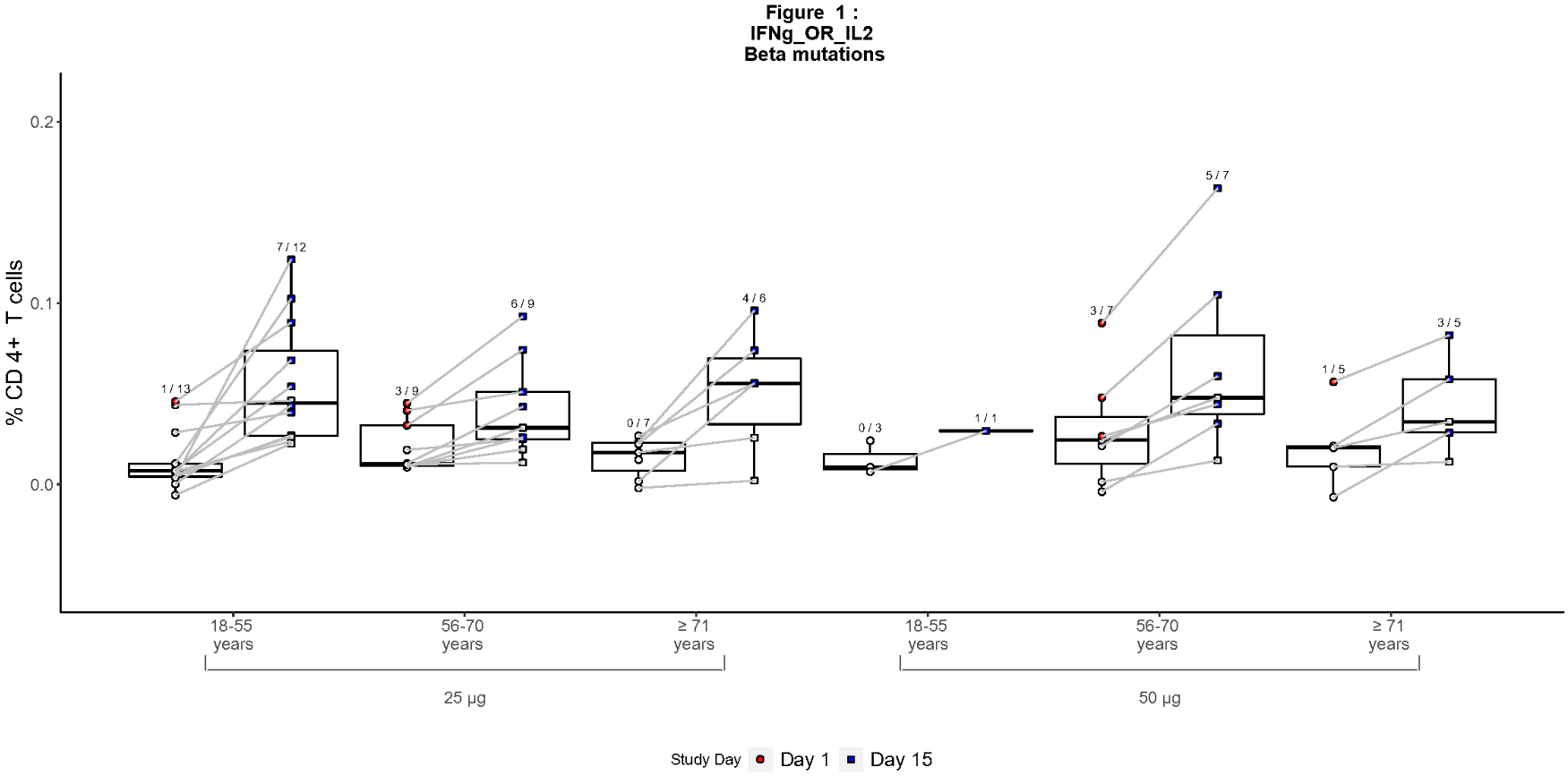
Figure 686: Correlation Heatmap, D614G – mITT Population, Treatment Arms 2C-H (Two Vaccinations)



Figures with Similar Format:

Figure 698: Percentages of CD4 T Cells Expressing IFNγ or IL-2, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

[Implementation note: Below is a sample figure. There will be two panels (2 rows, 1 column) for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422.]



Note: Open symbols represent Non-responders and closed symbols represent responders. Plots are annotated with Responder Rate.

Figures with Similar Format:

Figure 699: Percentages of CD4 T Cells Expressing IFNγ or IL-2, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 700: Percentages of CD4 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 701: Percentages of CD4 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 702: Percentages of CD4 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 703: Percentages of CD4 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 704: Percentages of CD4 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 705: Percentages of CD4 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 706: Percentages of CD4 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 707: Percentages of CD4 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 708: Percentages of CD4 T Cells Expressing IFNγ or IL-2 and 154, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

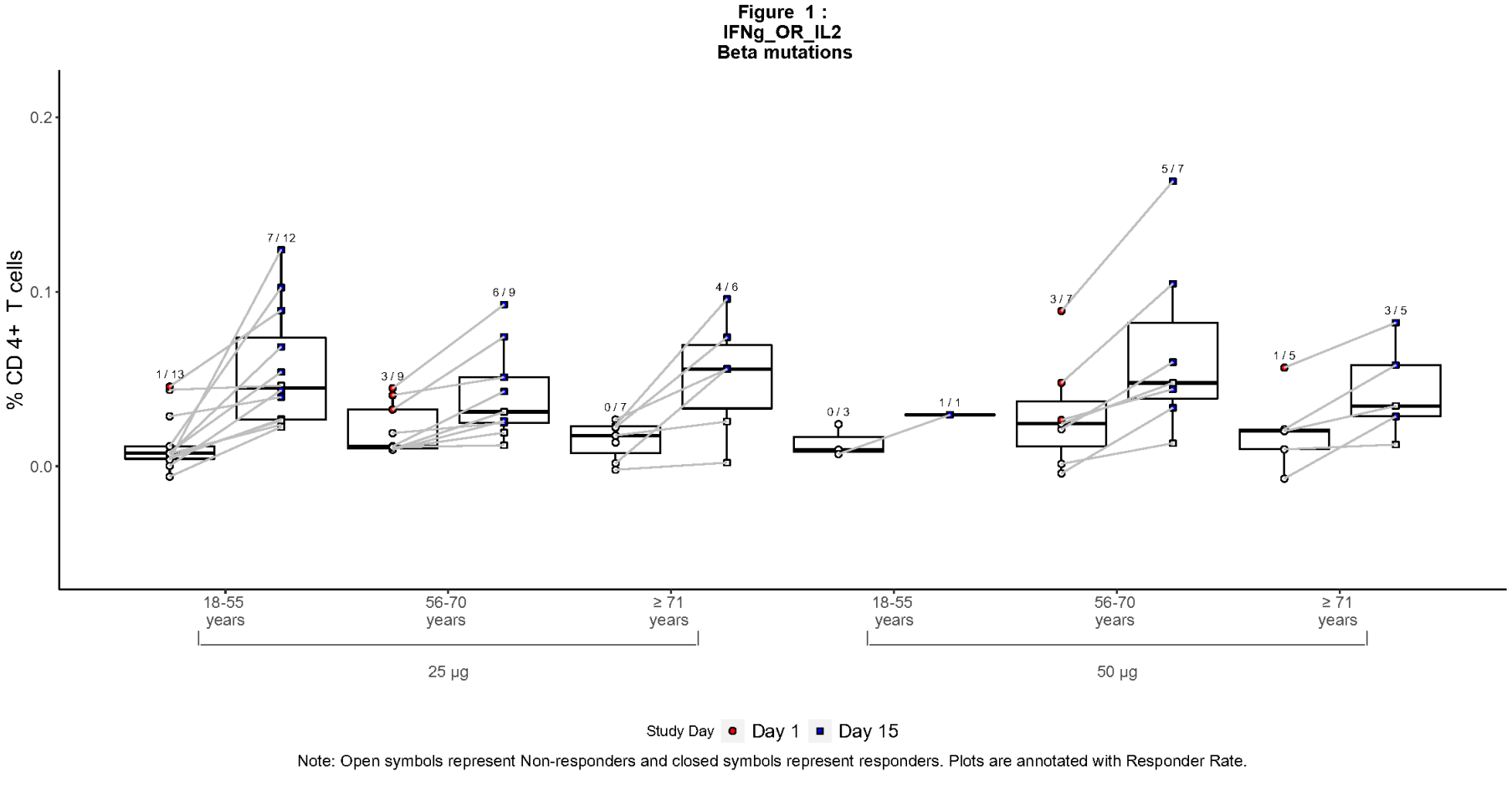
Figure 709: Percentages of CD4 T Cells Expressing IFNγ or IL-2 and 154, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 710: Percentages of CD4 T Cells Expressing IFNγ or IL-2 or 154, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 711: Percentages of CD4 T Cells Expressing IFNγ or IL-2 or 154, Beta Mutations – Per Protocol Population, Treatment Arms 2A-B (Three Vaccinations)

Figure 914: Percentages of CD4 T Cells Expressing IFNγ or IL-2, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

[Implementation note: Below is a sample figure. There will be six panels (2 rows, 3 columns) for the six two-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 91, 209, and 394.]



Note: Open symbols represent Non-responders and closed symbols represent responders. Plots are annotated with Responder Rate.

Figures with Similar Format:

Figure 915: Percentages of CD4 T Cells Expressing IFNγ or IL-2, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 916: Percentages of CD4 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 917: Percentages of CD4 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 918: Percentages of CD4 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 919: Percentages of CD4 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 920: Percentages of CD4 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 921: Percentages of CD4 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 922: Percentages of CD4 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 923: Percentages of CD4 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 924: Percentages of CD4 T Cells Expressing IFNγ or IL-2 and 154, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

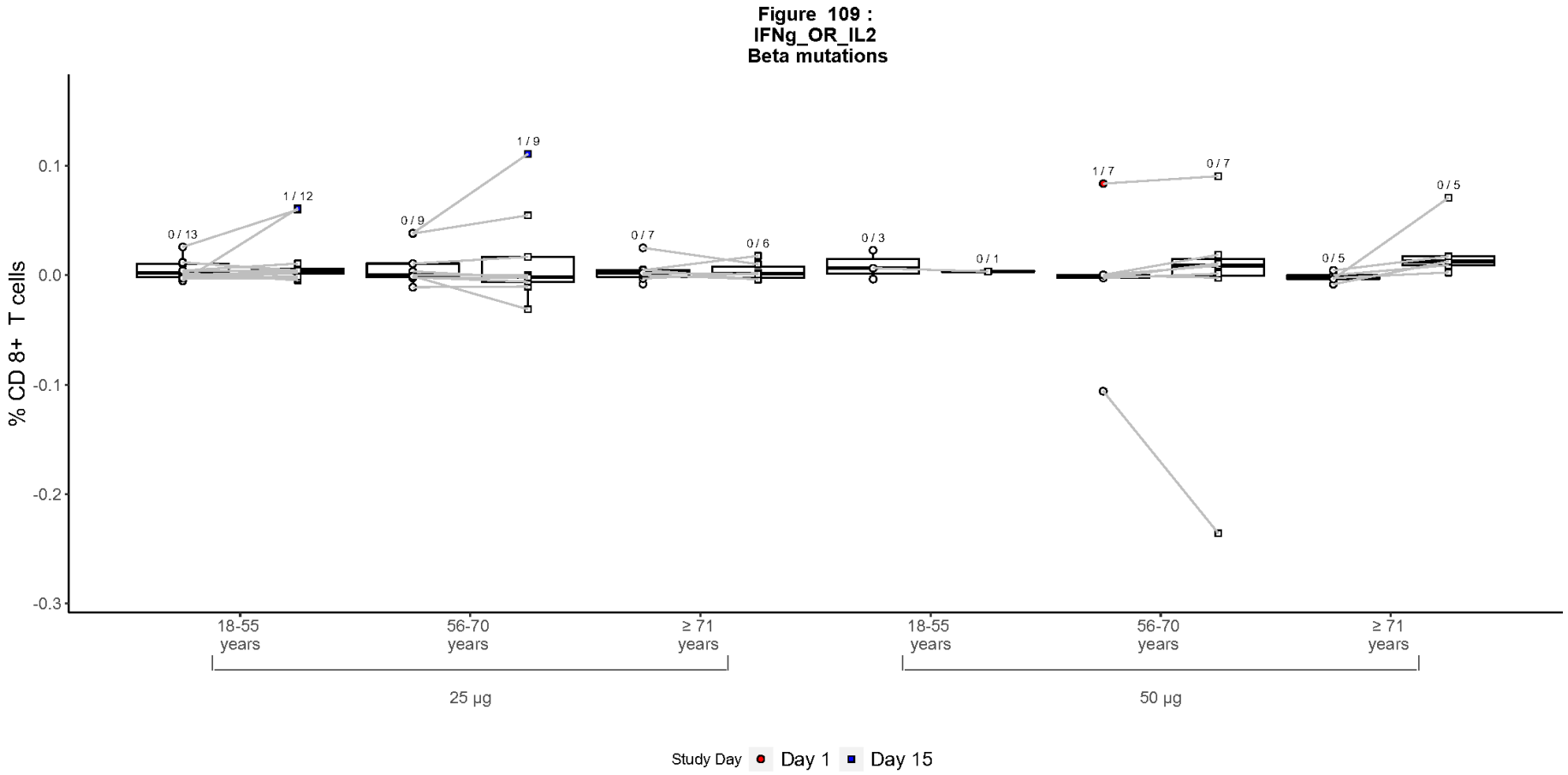
Figure 925: Percentages of CD4 T Cells Expressing IFNγ or IL-2 and 154, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 926: Percentages of CD4 T Cells Expressing IFNγ or IL-2 or 154, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 927: Percentages of CD4 T Cells Expressing IFNγ or IL-2 or 154, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1130: Percentages of CD8 T Cells Expressing IFNγ or IL-2, Beta Mutations – mITT Population, Treatment Arms 2A-B (Three Vaccinations)

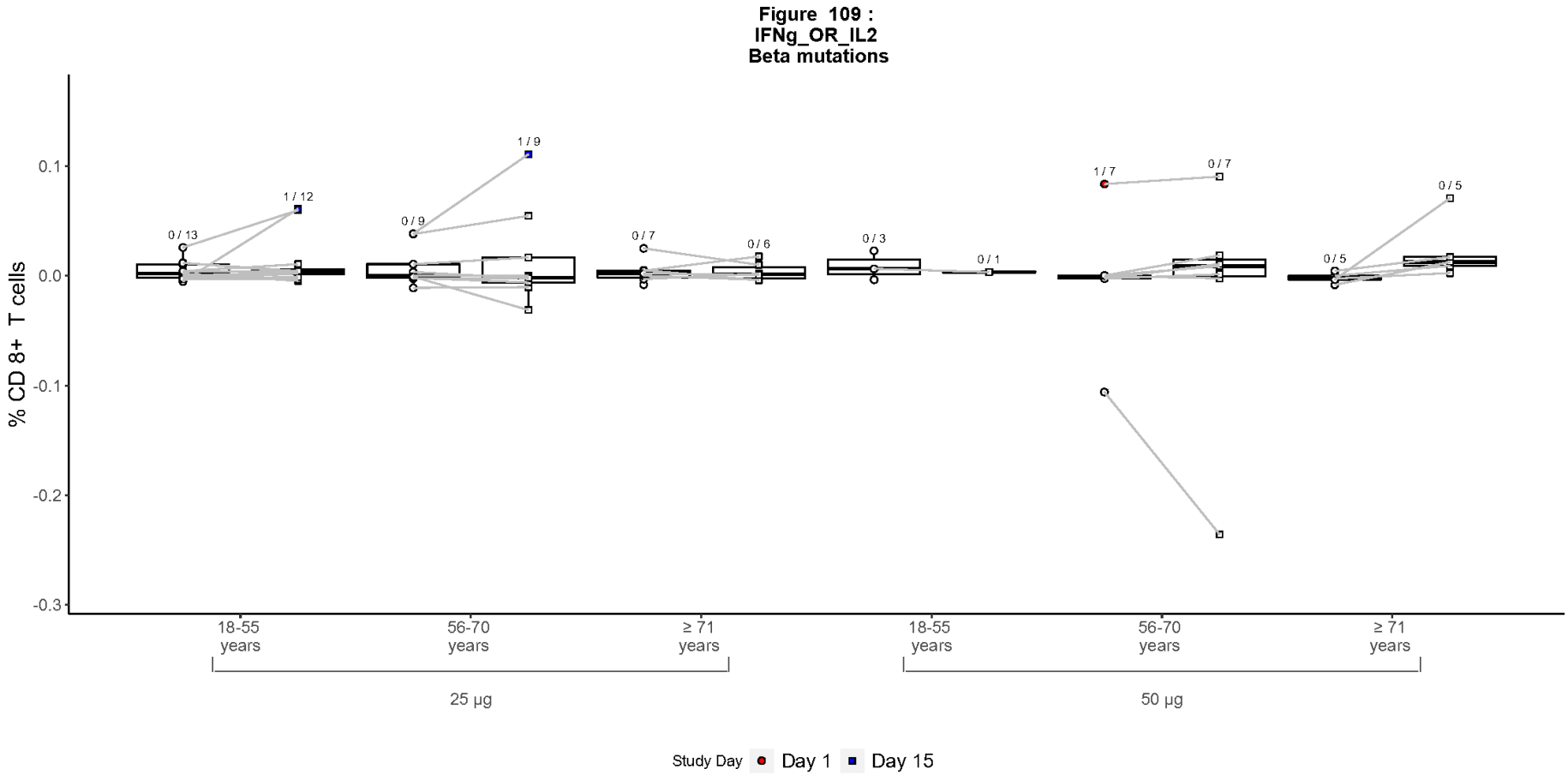
[Implementation note: Below is a sample figure. There will be two panels (2 rows, 1 column) for the two three-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 71, 85, 147, 237, and 422.]



Figures with Similar Format:

Figure 1190: Percentages of CD8 T Cells Expressing IFNγ or IL-2, Beta Mutations – mITT Population Treatment Arms 2C-H (Two Vaccinations)

[Implementation note: Below is a sample figure. There will be six panels (2 rows, 3 columns) for the six two-vaccination cohort 2 groups on Days 1, 15, 29, 43, 57, 91, 209, and 394.]



Figures with Similar Format:

Figure 1191: Percentages of CD8 T Cells Expressing IFNγ or IL-2, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1192: Percentages of CD8 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1193: Percentages of CD8 T Cells Expressing IFNγ or IL-2/CM, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1194: Percentages of CD8 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1195: Percentages of CD8 T Cells Expressing IFNγ or IL-2/EM, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1196: Percentages of CD8 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1197: Percentages of CD8 T Cells Expressing IFNγ or IL-2/N, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1198: Percentages of CD8 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1199: Percentages of CD8 T Cells Expressing IFNγ or IL-2/TD, Beta Mutations – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1200: Percentages of CD8 T Cells Expressing IFNγ or IL-2, Beta S – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1201: Percentages of CD8 T Cells Expressing IFNγ or IL-2, Beta S – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1202: Percentages of CD8 T Cells Expressing IFNγ or IL-2/CM, Beta S – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1203: Percentages of CD8 T Cells Expressing IFNγ or IL-2/CM, Beta S – Per Protocol Population, Treatment Arms 2C-H (Two Vaccinations)

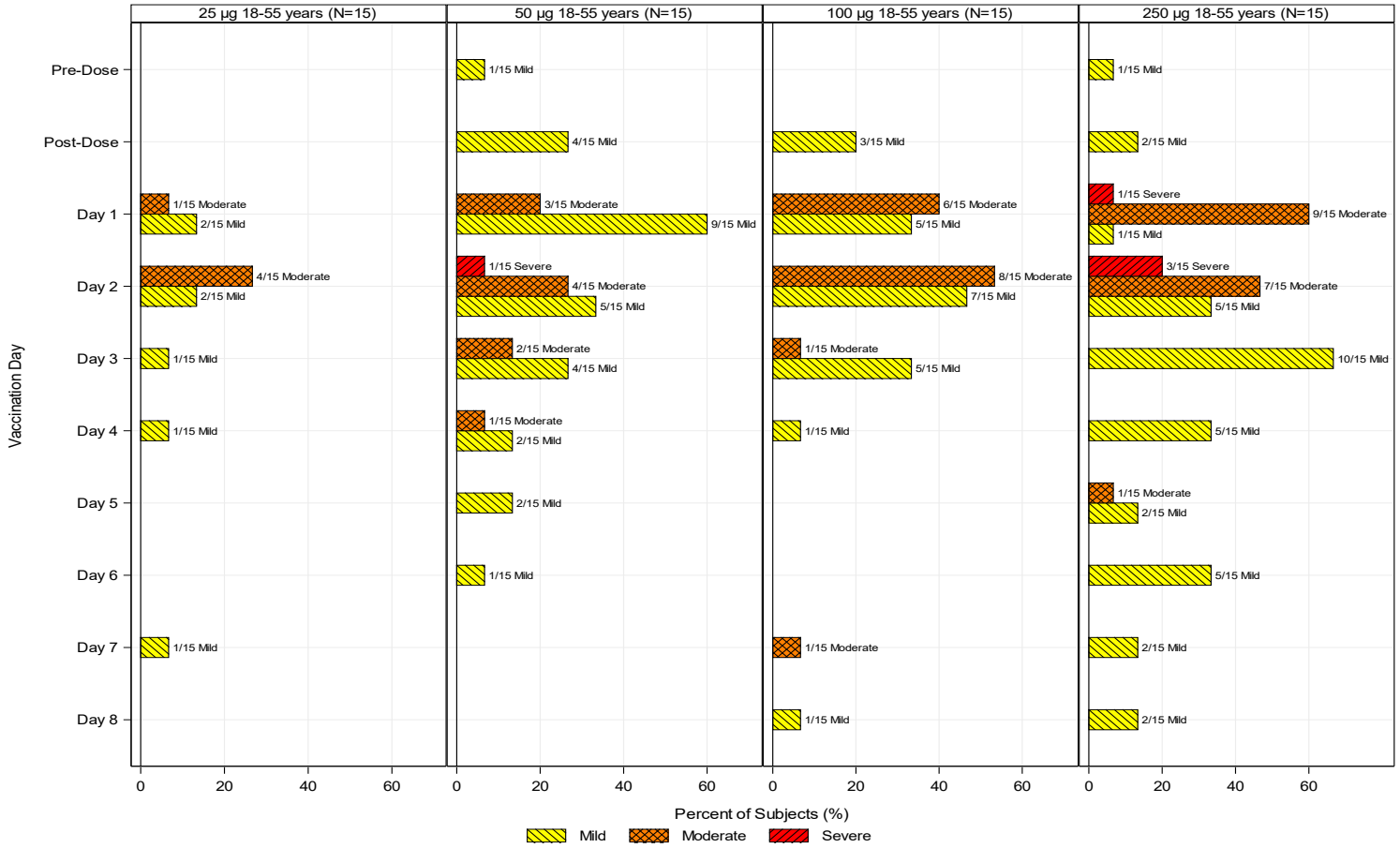
Figure 1204: Percentages of CD8 T Cells Expressing IFNγ or IL-2/EM, Beta S – mITT Population, Treatment Arms 2C-H (Two Vaccinations)

Figure 1205: Percentages of CD8 T Cells Expressing IFNγ or IL-2/EM, Beta S – Per Protocol Population, Treatment Arms 2C-H

14.3.1.1 Solicited Adverse Events

Figure 1250: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 1

[Implementation Note: Panels will only be shown for the eight Cohort 2 groups.]



Figures with Similar Format:

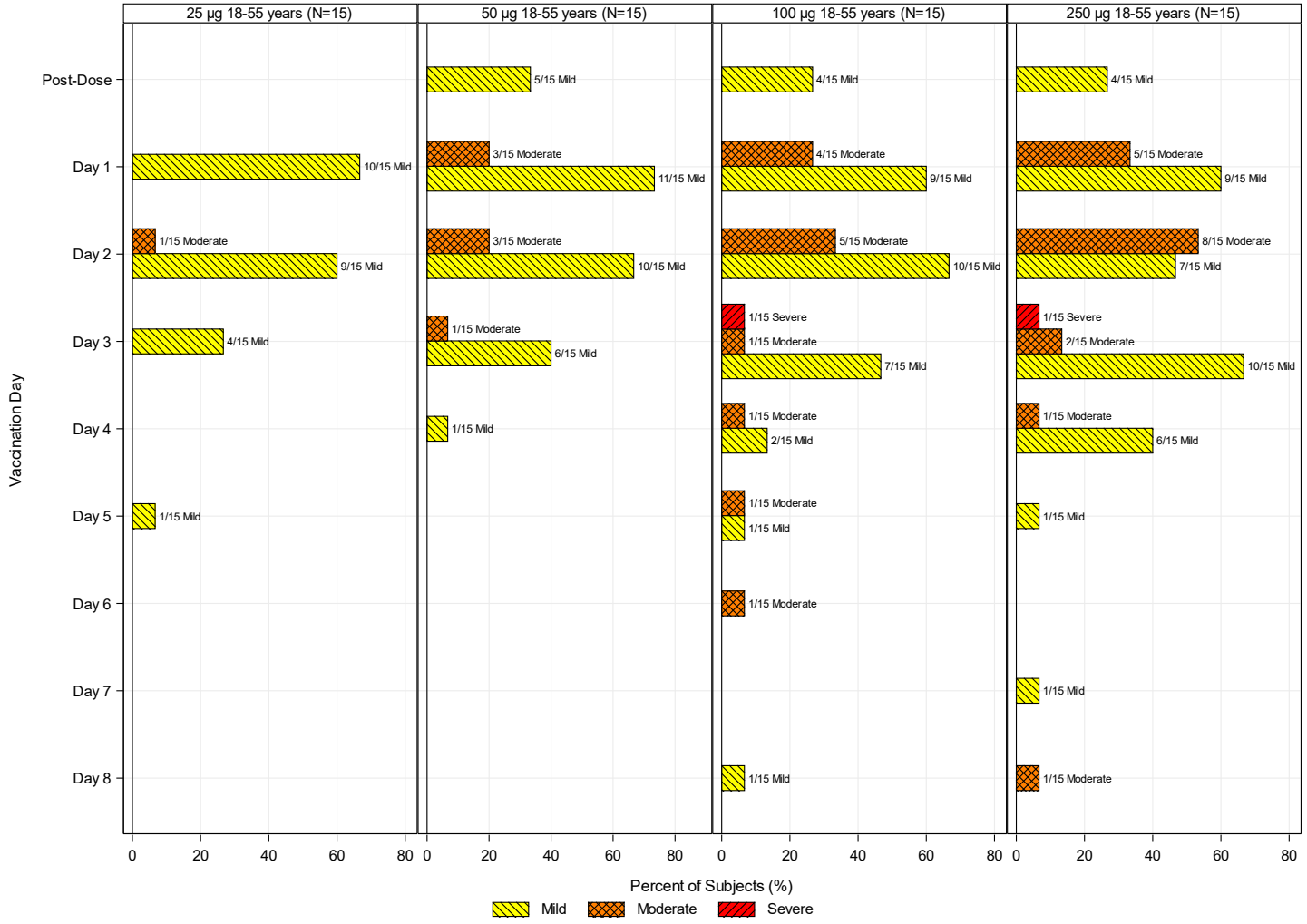
Figure 1251: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 2

Figure 1252: Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 3

[Implementation note: This figure will only have two panels for Arms 2A-B.]

Figure 1253: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 1

[Implementation Note: Panels will only be shown for the eight Cohort 2 groups.]



Figures with Similar Format:

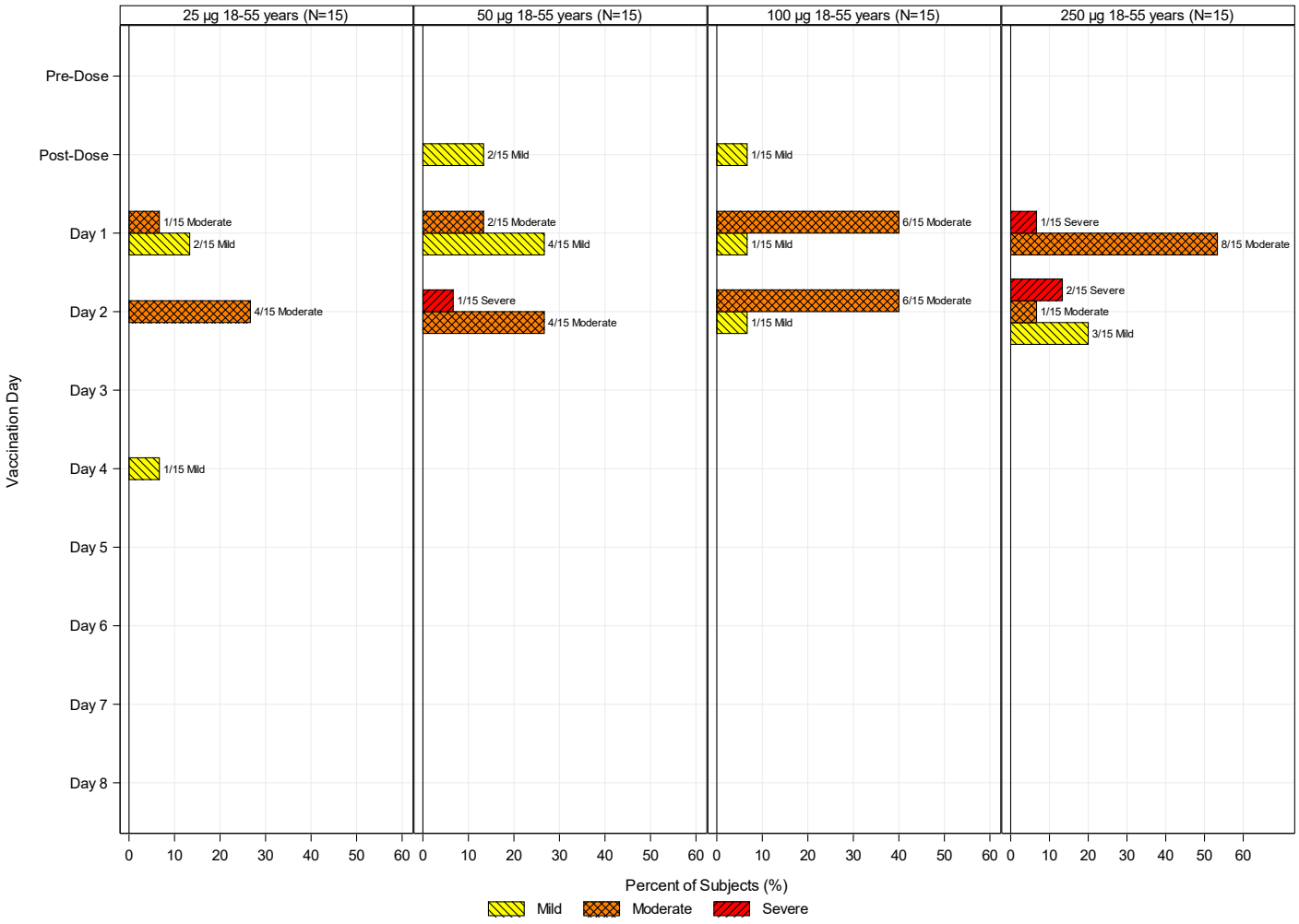
Figure 1254: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 2

Figure 1255: Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 3

[Implementation note: This figure will only have two panels for Arms 2A-B.]

Figure 1256: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 1

[Implementation Note: Panels will only be shown for the eight Cohort 2 groups.]



Figures with Similar Format:

Figure 1257: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 2

Figure 1258: Onset of Solicited Systemic Symptoms by Days Post Vaccination and Treatment Group – Post Dose 3

[Implementation note: This figure will only have two panels for Arms 2A-B.]

Figure 1259: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 1

Figure 1260: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 2

Figure 1261: Onset of Solicited Local Symptoms by Days Post Vaccination and Treatment Group – Post Dose 3

[Implementation note: This figure will only have two panels for Arms 2A-B.]

Figure 1262: Solicited Symptoms by Days Post Vaccination and Treatment Group – Arthralgia

[Implementation note: Figure should be three columns with plots for each treatment arm. The third column (for Dose 3) will have plots for arms A and B only.]

Figures with Similar Format:

Figure 1263: Solicited Symptoms by Days Post Vaccination and Treatment Group – Feverishness

Figure 1264: Solicited Symptoms by Days Post Vaccination and Treatment Group – Erythema

Figure 1265: Solicited Symptoms by Days Post Vaccination and Treatment Group – Erythema (mm)

Figure 1266: Solicited Symptoms by Days Post Vaccination and Treatment Group – Fatigue

Figure 1267: Solicited Symptoms by Days Post Vaccination and Treatment Group – Fever

Figure 1268: Solicited Symptoms by Days Post Vaccination and Treatment Group – Headache

Figure 1269: Solicited Symptoms by Days Post Vaccination and Treatment Group – Induration

Figure 1270: Solicited Symptoms by Days Post Vaccination and Treatment Group – Induration (mm)

Figure 1271: Solicited Symptoms by Days Post Vaccination and Treatment Group – Myalgia

Figure 1272: Solicited Symptoms by Days Post Vaccination and Treatment Group – Nausea

Figure 1273: Solicited Symptoms by Days Post Vaccination and Treatment Group – Pain

14.3.1.2 Unsolicited Adverse Events

Figure 1274: Frequency of Adverse Events by MedDRA System Organ Class and Severity

[Implementation Note: Figure should have columns for all eight treatment arms.]

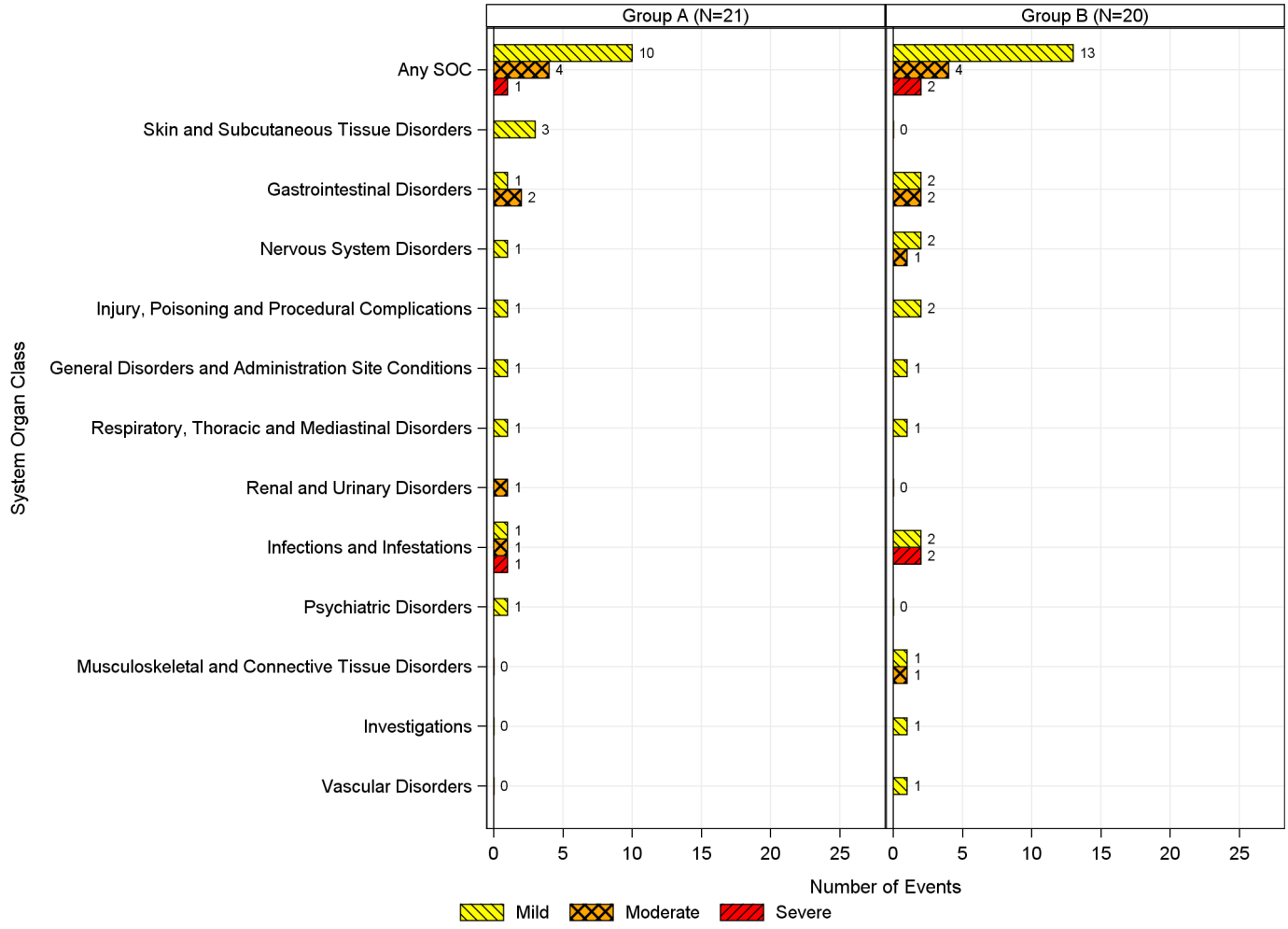
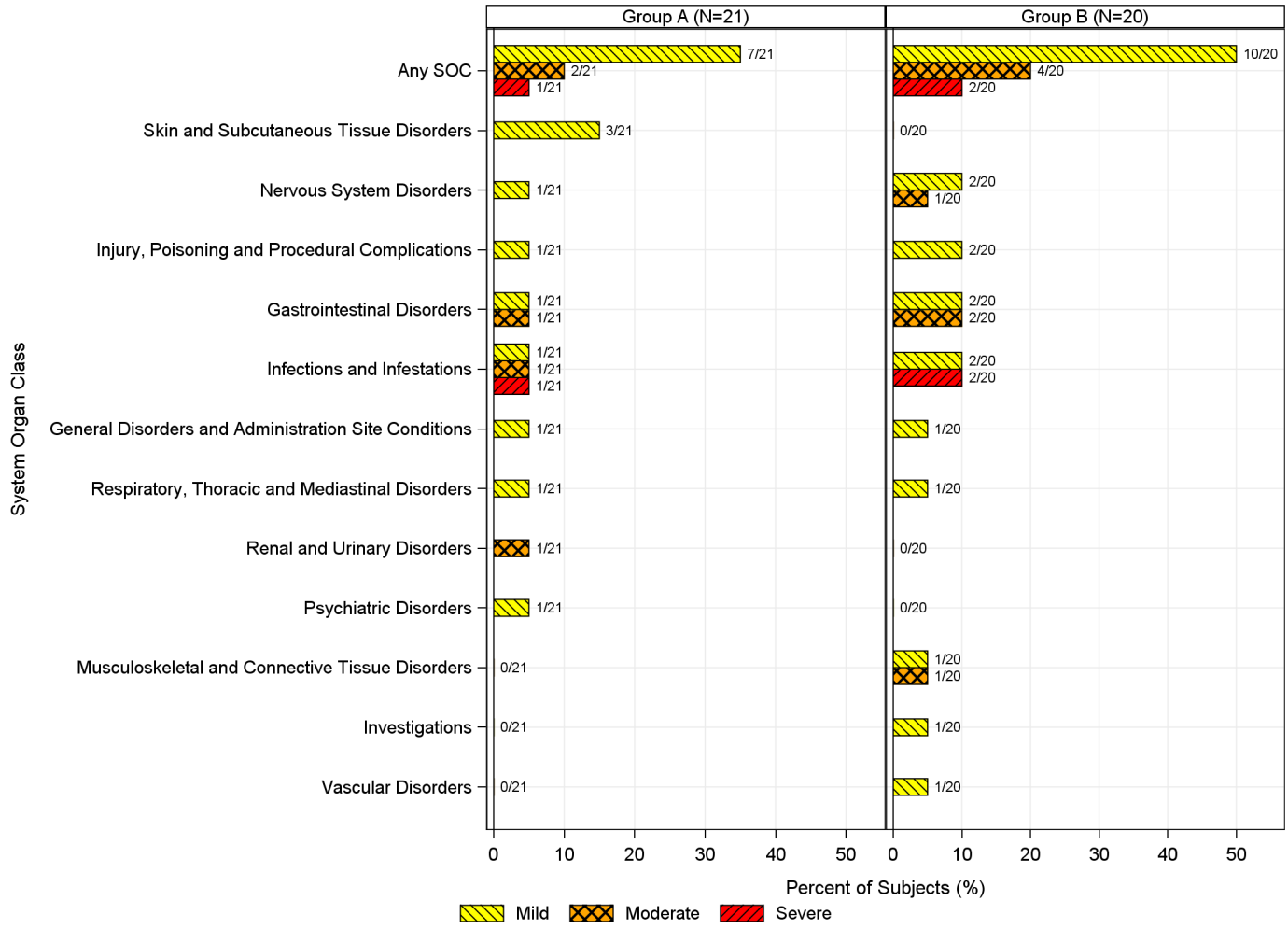


Figure 1275: Incidence of Adverse Events by MedDRA® System Organ Class and Maximum Severity

[Implementation Note: Figure should have columns for all eight treatment arms.]



14.3.5 Displays of Laboratory Results

Not Applicable.

APPENDIX 3. LISTINGS MOCK-UPS

LISTINGS

Listing 1: 16.1.6: Listing of Subjects Receiving Investigational Product

(not included in SAP, but this is a placeholder for the CSR)

16.2 Database Listings by Subject

16.2.1 Discontinued Subjects

Listing 2: 16.2.1: Early Terminations or Discontinued Subjects

Treatment Group	Subject ID	Category	Reason for Early Termination or Treatment Discontinuation	Study Day

16.2.2 Protocol Deviations

Listing 3: 16.2.2.1: Subject-Specific Protocol Deviations

Treatment Group	Subject ID	DV Number	Deviation	Deviation Category	Deviation Severity	Study Day	Reason for Deviation	Deviation Resulted in AE?	Deviation Resulted in Subject Termination?	Deviation Affected Product Stability?	Deviation Resolution	Comments

Listing 4: 16.2.2.2: Non-Subject-Specific Protocol Deviations

Site	Deviation Number	Deviation	Deviation Severity	Reason for Deviation	Deviation Resulted in Subject Termination?	Deviation Affected Product Stability?	Deviation Category	Deviation Resolution	Comments

16.2.3 Subjects Excluded from the Efficacy Analysis

Listing 5: 16.2.3: Subjects Excluded from Analysis Populations

Treatment Group	Subject ID	Analyses in which Subject is Included	Analyses from which Subject is Excluded	Results Available?	Reason Subject Excluded
		[e.g., Safety, ITT, PP]	[e.g., Safety, ITT, PP, Day x]		

Note: "Yes" in the "Results available" column indicates that available data were removed from the analysis. "No" indicates that no data were available for inclusion in the analysis.

16.2.4 Demographic Data

Listing 6: 16.2.4.1: Demographic Data

Treatment Group	Subject ID	Sex	Age at Enrollment (years)	Ethnicity	Race	BMI

Listing 7: 16.2.4.2: Pre-Existing and Concurrent Medical Conditions

Treatment Group	Subject ID	MH Number	Medical History Term	Condition Start Day	Condition End Day	MedDRA System Organ Class	MedDRA Preferred Term

16.2.5 Compliance and/or Drug Concentration Data (if available)

Not Applicable.

16.2.6 Individual Immunogenicity Response Data

Listing 8: 16.2.6: Individual Immunogenicity Response Data

Treatment Group	Subject ID	Planned Time Point	Actual Study Day	Assay	Units	Results

Listing 9: 16.2.6: Individual T-cell Response Data

Treatment Group	Subject ID	Planned Time Point	Actual Study Day	T-Cell	Peptide Pool	Cytokine	Adjusted Percent	Responder (Y/N)

16.2.7 Adverse Events

Listing 10: 16.2.7.1: Solicited Events – Systemic Symptoms

Treatment Group	Subject ID	Post Dose Day	Assessment[a]	Symptom	Severity	Attributed to Alternate Etiology?[b]	Alternate Etiology
			MA				
			Clinic				

[a] MA = Data reported by subject on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.

[b] Grade 3 events only.

Note: Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

Listing 11: 16.2.7.2: Solicited Events – Local Symptoms

Treatment Group	Subject ID	Post Dose Day	Assessment[a]	Symptom	Severity
			MA		
			Clinic		

[a] MA = Data reported by subject on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.

Note: Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

Listing 12: 16.2.7.3: Unsolicited Adverse Events

Adverse Event	Associated with Dose No.	No. of Days Post Associated Dose (Duration)	Severity	SAE?	Relationship to Study Treatment	In Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: , Subject ID: , AE Number:											
Comments:											
Treatment Group: , Subject ID: , AE Number:											
Comments:											
Note: For additional details about SAEs, see Table: xx.											

16.2.8 Individual Laboratory Measurements

Not Applicable.

16.2.9 Vital Signs and Physical Exam Findings

Listing 13: 16.2.9.1: Vital Signs

Treatment Group	Subject ID	Planned Time Point	Actual Study Day	Temperature (°C)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Heart Rate (beats/min)	Weight (kg)	Height (cm)

Listing 14: 16.2.9.2: Physical Exam Findings

Treatment Group	Subject ID	Visit Number	Body System	Interpretation	If Abnormal, Findings	If Abnormal, Reported as an AE?

16.2.10 Concomitant Medications

Listing 15: 16.2.10: Concomitant Medications

Treatment Group	Subject ID	CM Number	Medication	Medication Start Day	Medication End Day	Indication	Taken for an AE? (AE Description; Number)	Taken for a condition on Medical History? (MH Description; Number)	ATC Level 1 (ATC Level 2)

16.2.11 Pregnancy Reports

Listing 16: 16.2.11.1: Pregnancy Reports – Maternal Information

Treatment Group	Subject ID	Pregnancy Number	Study Day Corresponding to Estimated Date of Conception	Source of Maternal Information	Pregnancy Status	Mother's Pre-Pregnancy BMI	Mother's Weight Gain During Pregnancy	Tobacco, Alcohol, or Drug Use During Pregnancy?	Medications During Pregnancy?	Maternal Complications During Pregnancy?	Maternal Complications During Labor, Delivery, or Post-Partum?
Note: Maternal Complications are included in the Adverse Event listing. Medications taken during pregnancy are included in the Concomitant Medications Listing.											

Listing 17: 16.2.11.2: Pregnancy Reports – Gravida and Para

			Live Births												
Subject ID	Pregnancy Number	Gravida	Extremely PB[a]	Very Early PB[a]	Early PB[a]	Late PB[a]	Early TB[b]	Full TB[b]	Late TB[b]	Post TB[b]	Still Births	Spontaneous Abortion/ Miscarriage	Elective Abortions	Therapeutic Abortions	Major Congenital Anomaly with Previous Pregnancy?
Note: Gravida includes the current pregnancy, para events do not.															

[a] Preterm Birth
[b] Term Birth

Listing 18: 16.2.11.3: Pregnancy Reports – Live Birth Outcomes

Subject ID	Pregnancy Number	Fetus Number	Pregnancy Outcome (for this Fetus)	Fetal Distress During Labor and Delivery?	Delivery Method	Gestational Age at Live Birth	Size for Gestational Age	Apgar Score, 1 minute	Apgar Score, 5 minutes	Cord pH	Congenital Anomalies?	Illnesses/ Hospitalizations within 1 Month of Birth?
Note: Congenital Anomalies are included in the Adverse Event listing.												

Listing 19: 16.2.11.4: Pregnancy Reports – Still Birth Outcomes

Subject ID	Date of Initial Report	Fetus Number	Pregnancy Outcome (for this Fetus)	Fetal Distress During Labor and Delivery?	Delivery Method	Gestational Age at Still Birth	Size for Gestational Age	Cord pH	Congenital Anomalies?	Autopsy Performed?	If Autopsy, Etiology for Still Birth Identified?

Listing 20: 16.2.11.5: Pregnancy Reports – Spontaneous, Elective, or Therapeutic Abortion Outcomes

Subject ID	Date of Initial Report	Fetus Number	Pregnancy Outcome (for this Fetus)	Gestational Age at Termination	Abnormality in Product of Conception?	Reason for Therapeutic Abortion