Statistical Analysis Plan

Protocol Number: MVX0003

A follow-on study to assess the safety and immunogenicity of a booster dose of GBS-NN/NN2 vaccine, 1 to 5 years after GBS-NN/NN2 recipients in study MVX0002 have completed the primary vaccination course, in comparison with a single dose of GBS-NN/NN2 administered in placebo participants from study MVX0002 or vaccine naïve participants

Simbec-Orion Protocol ID: RD 751/34984

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CONFIDENTIAL

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Final 1.0	[redacted]

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Author: [redacted]
Version: Final 1.0

The undersigned have reviewed and revised this SAP and find it to be consistent with the study requirements:

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Signing Time: 09-Sep-2022 | 11:15 BST
F3E94C122FE94BD1802DA6C1E65CE70F

09-Sep-2022 | 11:15 BST

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Signing Reason: I approve this document
Signing Time: 09-Sep-2022 | 11:28 BST
B4FBBAAC77C3402EB63B5F1F6A964DB3

09-Sep-2022 | 11:28 BST

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Signing Reason: I approve this document
Signing Time: 09-Sep-2022 | 12:28 BST
E52D5091E1F34A3C883463AB44FB4D67

09-Sep-2022 | 12:28 BST

[redacted], CMO, MinervaX — Date

DocuSigned by:
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Signing Reason: I approve this document
Signing Time: 09-Sep-2022 | 13:35 CEST
96FA693EAE7F47B39C06240874D69B85

09-Sep-2022 | 13:35 CEST

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GLOSSARY OF ABBREVIATIONS

aCRF	Annotated Case Report Form
ADaM	Analysis Data Model
AE	Adverse Event
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
BMI	Body Mass Index
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Clinical Research Organisation
CS	Clinically Significant
CSR	Clinical Study Report
DBL	Database Lock
DMP	Data Management Plan
DRM	Data Review Meeting
ECG	Electrocardiogram
GBS-NN	Group B Streptococcus Vaccine (Component No I)
GBS-NN2	Group B Streptococcus Vaccine (Component No 2)
GM	Geometric Mean
h	Hours
ICH	International Conference on Harmonisation
IG	Immunogenicity
IgG	Immunoglobulin G
IMP	Investigational Medicinal Product
LS Mean	Least Squares Mean
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
ml	Millilitre
N	Number of subjects in the analysis set
n	Number of subjects with non-missing observations
NCS	Not clinically significant
[redacted]	[redacted]
PD	Pharmacodynamics
PK	Pharmacokinetics
PP	Per Protocol
PT	Preferred Term
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SE	Standard Error
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TFL	Tables, Figures and Listings
TMF	Trial Master File
µg	Microgram

1 INTRODUCTION

1.1 GENERAL

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under MinervaX ApS Protocol MVX0003 Version 5.0 dated 20 Jan 2022 and should be read in conjunction with the study protocol and electronic case report form (eCRF).

This version of the plan has been developed using protocol version 5.0 dated 20 Jan 2022 and annotated eCRF version 2.0 dated 08 Sep 2021. Any further changes to the protocol or eCRF will be reviewed for potential impact on the SAP which will be amended if it is deemed necessary.

Draft versions of the SAP will undergo review by the Statistical Reviewer, Statistical Programmer, Project Manager, Principal Investigator and the Sponsor/Sponsor representative. The analysis plan will be finalised and approved by the Sponsor prior to Database Lock (DBL).

1.2 CHANGES FROM PROTOCOL

- For clarification purposes, it should be noted that although the protocol describes the comparisons between immunogenicity data obtained from the current study to those obtained from the MVX0002 study (also included in section 11.5.1 of the SAP), there is no study objective associated with this.

- The protocol does not contain definitions for systemic or local reactogenicity. Definition of systemic and local reactogenicity added to the SAP for the purposes of the analysis.

1.3 CHANGES FROM PREVIOUS VERSIONS OF THE SAP

Not applicable.

2 STUDY OBJECTIVES

Primary Objective:

- To evaluate the safety over 12 weeks of a single booster dose of the GBS vaccine GBS-NN/NN2, administered 1 to 5 years after completion of the initial primary vaccination course and in comparison to vaccine naïve subjects (either placebo recipients from study MVX0002 or new vaccine naïve subjects).

Secondary Objectives:

- Safety Objectives: To evaluate the long-term safety profile of the GBS-NN/NN2 vaccine 6 months following the booster dose in comparison to vaccine naïve subjects (either placebo recipients from study MVX0002 or new vaccine naïve subjects) who have received a single first dose of GBS-NN/NN2 vaccine.

- Immunological Objectives:
    - To evaluate the IgG antibody responses, specific to GBS-NN and GBS-NN2 fusion proteins, on Day 1 and Day 85, in previously vaccinated healthy female subjects, and in comparison to vaccine naïve subjects (either placebo recipients from study MVX0002 or new vaccine naïve subjects) who have received a single first dose of GBS-NN/NN2 vaccine.
    - To evaluate the IgG antibody responses, specific to AlpCN, RibN, Alp1N and Alp2-3N, on days 1, 8, 29, 57, 85 and 183, in previously vaccinated healthy female subjects and in comparison to vaccine naïve subjects (either placebo recipients from study MVX0002 or new vaccine naïve subjects) who have received a single first dose of GBS-NN/NN2 vaccine.

Exploratory Objectives:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

3 STUDY DESIGN

3.1 OVERVIEW

This is an open label vaccine booster follow-up study. Subjects who have received a primary course of GBS-NN/NN2 or placebo in Study MVX0002 will be invited to return to receive a booster dose (or first dose in the case of placebo or vaccine naïve subjects) 1 to 5 years after the completion of the primary course of vaccination. All subjects will receive a single dose of GBS-NN/NN2 containing 50 µg of each fusion protein.

A minimum of 30 and a maximum of 40 female subjects will be recruited, comprised of between 20 and 30 subjects who had received previous vaccination with GBS-NN/NN2 in the MVX0002 study and up to 10 subjects who had received placebo in the MVX0002 study. If an insufficient number (<5) of previous placebo recipient subjects return to this study, vaccine naïve subjects will be recruited.

The study will include 7 visits (Visit 1: Screening Period, Visits 2-6: Treatment Period and Visit 7: Post-study Follow-up).

Post-recruitment note: 17 subjects who previously received active drug during study MVX0002, 5 subjects who previously received placebo during study MVX0002 and 5 vaccine naïve subjects were recruited and enrolled onto the study.

3.2 INCLUSION AND EXCLUSION CRITERIA

To be eligible for inclusion into this study, each subject must fulfil all inclusion criteria and not violate any exclusion criteria (for the protocol under which they are entered) during screening prior to enrolment. Details of the inclusion and exclusion criteria are presented within the protocol (section 10.4).

3.3 STUDY TREATMENT

All subjects will receive a single 0.5 mL intramuscular injection of GBS-NN/NN2 containing 50 µg of GBS-NN and 50 µg of GBS-NN2 on Day 1.

- GBS-NN/NN2 vaccine will be supplied as a pre-mixed vial containing 0.35 mg/mL each of GBS-NN and GBS-NN2, to be adsorbed to Alhydrogel® adjuvant supplied separately.

Administration will be by intramuscular injection, preferably into the deltoid muscle of non-dominant arm. The dominant arm may be used if it is not possible to administer into the non-dominant arm e.g., due to a tattoo.

3.4 STUDY TIMEPOINTS

	Screening Period	**Treatment Period**					**Safety Follow-Up**
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**
Assessment	Day -28 to Day -1	Day 1	Day 8 (±1day)	Day 29 (±2days)	Day 57 (±2days)	Day 85 (±5days)	Day 183 (±7days)
Informed Consent	X						
Inclusion/Exclusion Criteria	X						
Subject number and IMP received in MXV0002 study	X						
Demography	X						
Medical History	X						
Physical Examination[1]	X (Full)	X (Brief & SDPE)	X (Brief)	X (Brief)			X (Brief)
Height, Weight, BMI	X						
Vital Signs[2]	X	X	X	X	X	X	X
12-lead ECG	X						
Urinalysis	X						X
Laboratory Safety Tests (Biochemistry and Haematology)	X		X	X	X		X
Virology (HIV, HBsAg and HCV Ab)	X						
Pregnancy Test	X (Serum)	X (Urine)					X (Urine)
FSH[3]	X						
Urine DOA including alcohol and cotinine tests	X	X					
Review of Subject Elig bility		X					
Administration Investigational vaccine		X					
PD Blood Sample – Antibody Response[4]		X	X	X	X	X	X
Exploratory Blood Sample – [redacted]		X	X				
Blood sample for future work[6]				X	X	X	
Assessment of Injection Site[7]		X	X	X	X	X	

AE Check		X					
Concomitant Medication Check	X	X					
COVID-19 [8]		X					
Subject Diary Card Day 1 to Day 7[9]		X					
Subject Diary Card Day 85 to Day 183[10]						X	

Study Flow Chart Footnotes:

1. Physical examination: Full physical examination will be performed at Screening. A brief physical examination will be performed pre-dose on Day 1 and a Symptom-Directed Physical Examination (SDPE) will be performed prior to discharge at 30 min (±5 min) post-dose on Day 1. Brief physical examinations will also be conducted on Day 8, Day 29 and at the safety follow up visit (Day 183). A physical examination may also be conducted at any other timepoint during the study if clinically indicated.
2. Vital signs (Supine heart rate, blood pressure, tympanic temperature and respiration rate) will be measured at Screening, Day 1 (pre-dose and 30 min (±5 min) post dose), Day 8, Day 29, Day 57, Day 85 and Day 183.
3. For postmenopausal female subjects only.
4. PD blood samples (antibody response) will be collected on Day 1 (pre-dose), Day 8, Day 29, Day 57, Day 85, and Day 183. GBS-NN/GBS-NN2 will be analysed on Day 1 and Day 85 only.
5. Exploratory blood samples ([redacted]) will be collected on Day 1 (pre-dose) and Day 8.
6. Blood samples for future validation and calibration work will be collected on Day 29, Day 57, and Day 85.
7. Injection site assessment will be performed at pre-dose and 30 min (±5 min) post dose on Day 1, Day 8, Day 29, Day 57, and Day 85. Photographs may be taken of injection site reactions as required.
8. COVID-19 test to be performed at Visit 2, Day 1 (or at Visit 1, Day -1 as determined by the PI) if required.
9. Subject Diary Cards will be completed by subjects at home to record morning and evening temperatures, injection site reactions and general reactions, and any AEs and concomitant medication, from the evening of Day 1 to the evening of Day 7. On return to the clinic on Day 8, any out of range temperatures, reactions, AEs or concomitant medication will be recorded in the eCRF.
10. Subject Diary Cards will be completed by subjects at home to record any adverse events and concomitant medication from Day 85 to Day 183. On return to the clinic on Day 183, any AEs or concomitant medication will be recorded in the eCRF.

AE = adverse events, BMI = body mass index, ECG = electrocardiogram, HBsAg = hepatitis B surface antigen, HCV Ab = hepatitis C virus antibody, HIV = human immunodeficiency virus, [redacted], PD = pharmacodynamic

3.5 SAMPLE SIZE CONSIDERATIONS

Sample size calculation has not been assessed. It is limited by the number of subjects who have participated in study MVX0002 and are willing to participate for this study. Protocol requires a minimum of 30 and a maximum of 40 female subjects to be recruited, comprised of between 20 and 30 subjects who had received previous vaccination with GBS-NN/NN2 in the MVX0002 study and up to 10 subjects who had received placebo in the MVX0002 study. If an insufficient number (<5) of previous placebo recipient subjects return to this study, vaccine naïve subjects will be recruited.

A total of 27 subjects received a single 0.5 mL intramuscular injection of GBS-NN/NN2 containing 50 µg of GBS-NN and 50 µg of GBS-NN2 on Day 1, of which 17 subjects had previously received active drug during study MVX0002, 5 subjects previously received placebo during study MVX0002 and 5 subjects were vaccine naïve.

3.6 RANDOMISATION

This is an open label study. All subjects will receive a single intramuscular injection of GBS-NN/NN2 containing 50 µg of GBS-NN and 50 µg of GBS-NN2.

Subjects will be numbered sequentially from 001 (i.e., 001, 002 etc.). Replacement subjects will be assigned the same number as the subject they are replacing, however, 100 will be added to the number (i.e., 101 would replace 001 etc.).

4 STUDY VARIABLES AND COVARIATES

4.1 PRIMARY VARIABLES

The following endpoints will be evaluated to assess the safety over 12 weeks of a single booster dose of the GBS vaccine (GBS-NN/NN2):

- Local and systemic reactogenicity (as assessed by adverse events)
- Adverse events
- Laboratory safety parameters (biochemistry, hematology, urinalysis)
- Vital signs
- Physical examination

All the subjects evaluable for safety (including those subjects who have been withdrawn or dropped out) will be included in the safety analysis.

4.2 SECONDARY VARIABLES

The following secondary safety endpoints will be evaluated to assess the long-term safety profile of the GBS-NN/NN2 vaccine 6 months following the dose:

- the incidence of autoimmune diseases and/or clinically relevant medical events related to the vaccination that occur in the 6-month follow-up period.
- The following secondary immunological endpoints will be evaluated:
    - Individual subject antibody concentration specific for GBS-NN and GBS-NN2, in µg/mL, at Day 1 and Day 85.
    - Individual subject antibody concentration specific for AlpCN, RibN, Alp1N and Alp2-3N, in µg/mL, at Day 1, 15, 29, 57, 85 and 183.

From the endpoints listed above the following will be derived:

- Geometric mean fold increase in antibody concentration, specific for GBS-NN and GBS-NN2, between Day 1 and Day 85.
- Geometric mean fold increase in antibody concentration, specific for AlpCN, RibN, Alp1N and Alp2-3N, between Day 1 and Days 8, 29, 57, 85 and 183.
- Proportion of subjects achieving antibody concentrations, specific for AlpCN, RibN, Alp1N and Alp2-3N, above 0.5, 1, 2 and 4 µg/mL on Day 8, 29, 57, 85 and 183 .
- The values of these endpoints 84 days after the dose will be the basis of the primary immunological analysis; this timepoint is anticipated to be the time of delivery after vaccination in a pregnant woman.

The secondary endpoints relating to antibody concentrations specific for AlpCN, RibN, Alp1N and Alp2-3N and all exploratory endpoints will be analysed and reported separately. Full details of the analyses will be documented in a separate plan(s).

The values of these endpoints on Day 85 will be the basis of the primary immunological analysis. This timepoint is anticipated to be the time of delivery after vaccination in a pregnant woman.

4.3 EXPLORATORY VARIABLES

The exploratory PD endpoints for this study are as follows:

- [redacted]
- [redacted].

5 DEFINITIONS AND DERIVED VARIABLES

MVX0002 Treatment: Treatment received by each subject during the MVX0002 study, either placebo, 25 µg GBS-NN/NN2 or 50 µg GBS-NN/NN2.

Study Drug/Investigational Medicinal Product (IMP): Study Drug/IMP is a single 0.5 mL intramuscular injection of 50 µg GBS-NN/NN2.

Baseline: Baseline defined as last available value pre-dose.

Study Day: Study day is the number of days since start of treatment where the date of first dose is counted as Day 1.

Fold Increase: Ratio of antibody concentrations at particular visits.

Protocol Deviation: a deviation related to study inclusion or exclusion criteria, conduct of the trial, subject management or subject assessment. This refers to any change, divergence, or departure from the study design or procedures defined in the protocol. Protocol deviations captured in the eCRF will be discussed at the Data Review Meeting (DRM) before Database Lock (DBL). In addition, any deviations identified during the DRM will be discussed and included in the database as necessary. All protocol deviations within the study database will be classified as either 'Major' or 'Minor' prior to DBL, details of which will be included within the Protocol Deviations listing.

6 ANALYSIS SETS

Membership of the analysis sets will be reviewed during the DRM and agreed prior to DBL. These will be reviewed by the Sponsor, Study Statistician and Project Manager and included within the DRM minutes.

6.1 ALL CONSENTED SET

All subjects for whom informed consent was obtained will constitute the All Consented Set.

This analysis set will be used for study disposition and analysis set listings and summaries.

6.2 SAFETY SET

All enrolled subjects who receive the study vaccine will be included in the Safety Set.

This analysis set will be used for baseline and safety summaries as well as for all study listings.

6.3 IMMUNOGENICITY SET (IG)

The primary immunogenicity analysis will be performed on the Immunogenicity Set, which consists of all subjects who receive the study vaccine with available post-vaccination titres for Day 85.

In order for subjects who previously received GBX-NN/NN2 to be included in statistical comparisons of immune response data obtained from the MVX0002 and MVX0003 studies, a subject must be included in the IG Set for both studies.

6.4 PER PROTOCOL SET (PP)

All subjects included in the IG Set who do not violate the protocol in a way that may invalidate or bias the results.

The immunological analyses will primarily be performed on the IG Set but will also be performed on the PP set if the number of subjects in the PP set differs by more than 5% from that of the IG Set.

In order to be included in statistical comparisons of immune response data obtained from the MVX0002 and MVX0003 studies, a subject must be included in the PP Set for both studies.

7 SAFETY MONITORING

No interim safety reporting is planned for this study.

8 INTERIM ANALYSES

No interim analyses are planned for this study.

9 DATA

9.1 eCRF Data

Data captured in the eCRF will be provided by Simbec-Orion Data Management to the Statistics department as SAS datasets in a standard format. Study Data Tabulation Model (SDTM) datasets will be derived from the raw database and Analysis Data Model (ADaM) from SDTM. Both SDTM and AdaM domains will be used for programming the outputs to be included in the Clinical Study Report (CSR). Specifications of both SDTM and AdaM will be provided in a separate document. SDTM/AdaM programming will begin when populated SAS datasets are available.

9.2 EXTERNAL DATA

9.2.1 Laboratory Data

Transfers of safety laboratory data will be provided by Simbec-Orion Laboratory Services delivered to Simbec-Orion Data Management via electronic transfer and stored within the study database. Details of laboratory data are documented in the Laboratory Service Plan (LSP). Populated test transfers will be received before programming can start.

The following results will be included:

- **Hematology:** Red blood cell (erythrocyte) count, hemoglobin, HCT, platelet count, white blood cell (leukocytes) count with absolute differential (neutrophils, lymphocytes, monocytes, eosinophils, basophils which are reported in absolute and percentage values).

- **Biochemistry:** Sodium, potassium, chloride, bicarbonate, blood urea, creatinine, creatine kinase, glucose, calcium, albumin, cholesterol, C-reactive protein (CRP), triglycerides, phosphorus (inorganic phosphate), lactate dehydrogenase (LDH), total protein, globulin, uric acid, alkaline phosphatase (ALP), aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma glutamyl transferase (GGT), total bilirubin and direct bilirubin.

- **Urinalysis:** Specific gravity, pH, protein, glucose, ketones, occult blood, leukocyte esterase, nitrites.

- **Microscopy:** In the event that the urinalysis 'dipstick' test result is positive for nitrite and/or 2+ or more reported for protein, blood, and/or leucocytes, the parameters red blood cells, white blood cells, epithelial cells, crystals, bacteria and casts will be examined microscopically.

- **Virology:** HIV, HbsAg and HCV Ab.

- **Drugs of Abuse Screen and Alcohol:** Alcohol, cannabinoids, amphetamines, barbiturates, cocaine, benzodiazepines, methadone, phencyclidine, opiates and cotinine.

- **COVID-19 Test:** A nasopharyngeal and/or oropharyngeal swab will be collected.

- **Pregnancy Test:** Serum and urine pregnancy tests (human chorionic gonadotropin).

- **Post-menopausal Assessment:** Follicle-stimulating hormone.

- **Other Parameters:** Any further parameters that are taken at the request of the Investigator that are not included as part of the above categories will be included in an 'Other Laboratory Data' listing.

9.2.2 Antibody Titre Data

Antibody titre data (antibody concentration specific for GBS-NN/GBS-NN2) will be delivered to Simbec Data Management via electronic transfer from Simbec-Orion Laboratory Services and stored as a SAS dataset. These data will be stored in the appropriate analysis dataset.

9.2.3 MVX0002 Study Data

Information regarding study treatment allocation, analysis set inclusion and immune response data obtained from the MVX0002 study will be used to facilitate comparison of results between the MVX0002 and MVX0003 studies. The analysis datasets AD_SL and AD_PD will be merged with current MVX0003 study data using the subject number link captured within the DM dataset and incorpated into the appropriate SDTM and ADaM domains.

9.3 RANDOMISATION LIST

Not applicable.

9.4 PROGRAMMING AND DATA REVIEW

Programming of datasets, tables, figures and listings will be ongoing while study data management activities are in progress.

Prior to DBL, a review of the clinical database will be conducted. Outputs for the data review will be produced as Excel outputs of the clinical database. A DRM will be held to discuss the outcome of this review, any potential impact on the analyses, analysis sets and protocol deviations. The classification of adverse events as local and systemic reactogenicity effects, autoimmune diseases and clinically relevant AEs will also be discussed. Meeting minutes will be created which will include details of decisions surrounding analysis sets and protocol deviation classification. Once all data issues have been resolved, the analysis sets approved and protocol deviation classifications agreed, the database will be locked. The post-lock SDTM/AdaM datasets will be generated, the TFLs will be run and quality control (QC) will take place.

10 STATISTICAL METHODS

10.1 GENERAL PRINCIPLES

- All statistical methods will be based on the International Conference on Harmonisation (ICH) E9 document "Statistical Principles for Clinical Trials".

- Except for the [redacted] data and antibody concentrations specific for AlpCN, RibN, Alp1N and Alp2-3N, all data collected will be presented within data listings.
- Generally, data listings will be sorted by study (where applicable), treatment (where applicable), subject and visit.
- Generally, data will be summarised by study (where applicable), treatment (where applicable). Baseline data will be summarised overall. The format of the summaries is defined in the shells at the end of this document.
- Repeated visits will be denoted with 'RPT'. Unscheduled visits will be denoted with 'UNS'.
- In summary and analysis tables of continuous variables, standard descriptive statistics (N [number within analysis set, or group, or subgroup], n [number of observations included in analysis], mean, standard deviation [SD], median, minimum and maximum) will be presented. Least squares means (LSMean) and 90/95% confidence intervals (CI) will be presented in the statistical analysis outputs as appropriate.
- Unless otherwise specified, the minimum and maximum statistics will be presented in summary tables to the same number of decimal places as the original data. The mean, geometric mean, median, geometric LSMean, and CI will be presented to one more decimal place than the original data. SD will be presented to two more decimal places than the original data.
- Immunogenicity summaries will be presented to 3 significant figures for all parameters. Fold-increase data will be presented to two decimal places.
- In summary tables of categorical variables, the number of non-missing observations by category will be presented along with percentages. Unless otherwise specified, the denominator for each percentage will be the number of non-missing observations.
- All percentages will be presented to one decimal place.
- All plots will use a linear time scale for the nominal times of the visits and will be labelled by timepoint.
- For post-dose assessments, only data obtained from scheduled visits/timepoints will be used in summary tables. Post-dose repeat or unscheduled assessments will be listed only. For assessments occurring prior to dosing (i.e. Screening, Day 1 pre-dose), the last repeat assessment for each visit will be included in the summary tables and, where repeats of baseline values occur, the last assessment will be used to calculate change from baseline.
- Dates and times for all output presentations will be presented in ISO 8601 Datetime format.
- All outputs will present data in a format that complies with CDISC required terminology and codelists and the SAP will use American-English spelling in line with CDISC terminology, where appropriate (i.e. hematology).
- All statistical analysis will be performed using SAS EG v8.3 or higher.
- Generally, character values will be left aligned and numeric values will be decimally aligned.
- If no data are available for a specific output the output must still be produced stating an appropriate message indicating no data were present.
- For numeric data, which includes non-numeric values (e.g. PD data reported as BLQ or laboratory results reported as <10 or >100), the following principles will be applied when summarising the data:
  - Values reported as BLQ will be replace with ½ of LLOQ
  - Values reported as ALQ will be replace with ULQ
  - Results reported as <*x* or >*x* will be treated as *x*

10.2 STRATIFICATION AND COVARIATE ADJUSTMENT

Not applicable.

10.3 INTERACTIONS

Not applicable.

10.4 MISSING DATA

No methods to account for missing safety data will be used.

10.5 POOLING OF SITES

Not applicable.

10.6 MULTIPLE COMPARISONS

No adjustments for multiple comparisons are planned.

10.7 SUBGROUP ANALYSES

Not applicable.

10.8 STATISTICAL ISSUES

None.

11 STATISTICAL OUTPUT

General principles for layout of the statistical output are described in Section 10.1. Layout and specifications are illustrated for each unique table in the table shells in Section 14.

11.1 SUBJECT DISPOSITION

The subject disposition table will summarise the following data:

- The number screened
- The number of screening failures/non-runners
- The number of subjects dosed
- The number of subjects previously dosed with each MVX0002 treatment

- The number (%) of subjects who completed/withdrew from the study and the associated reasons for withdrawal
- The number (%) of subjects in each analysis set

All percentages will be calculated from the number of dosed subjects.

Screening and study completion/termination data (including informed consent information) will also be listed. A listing of all protocol deviations will be presented including major/minor classification. A data listing presenting subject eligibility for each analysis set and the reason for exclusion from an analysis set will also be presented.

Disposition data will be summarised and listed for all enrolled subjects.

11.2 SUBJECT CHARACTERISTICS AT BASELINE

11.2.1 Demographic and Baseline Characteristics

Demographic data will be listed and descriptive statistics for the continuous variables age, height, weight and body mass index (BMI) at Screening and frequencies for the categorical variables race and ethnicity will be tabulated by MVX0002 dose level, all active doses combined and overall.

Demographic data will be summarised using the Safety Set. Demographic characteristics will be also presented for other study populations (IG and/or PP) if they differ from the Safety Set.

11.2.2 Medical History and Concurrent Conditions

All Medical History data will be coded using the MedDRA dictionary using the version specified in the DMP.

Medical history events will be tabulated by System Organ Class (SOC) and Preferred Term (PT) for each MVX0002 dose level, all active doses combined and overall. A subject reporting multiple episodes of a particular Medical History will only contribute 1 count towards the corresponding SOC and PT.

All Medical History data will be summarised and listed using the Safety Set.

In the case of few Medical History events (≤5), only a listing will be created.

11.3 EFFICACY ANALYSES

Not applicable.

11.4 PK ANALYSES

Not applicable.

11.5 PD ANALYSES

Immunogenicity will be assessed using the Immunogenicity Set and will be repeated for the Per Protocol Set, should the analysis sets differ by more than 5% .

11.5.1 Antibody Response

Samples for determining the concentrations for immunoglobulin (IgG) antibodies to GBS-NN and GBS-NN2 will be collected on Day 1 and Day 85 (±5).

For the MVX0002 study, samples were collected on Day 1, Day 15, Day 29, Day 43, Day 57, Day 85, Day 210. For comparison with the MVX0003 study, antibody data obtained from study MVX0002 will only include those subjects who are also participating in MVX0003 and will be limited to Day 1 and Day 85.

Antibody titre responses (IgG concentrations [specific for GBS-NN and GBS-NN2]) will be listed for each subject along with their associated Day 1 and Day 85 results obtained from the MVX0002 study, where appropriate. Absolute and change from baseline (Day 1) antibody response data will be summarised descriptively using N, n, geometric mean and corresponding 95% confidence interval (CI), minimum, median, maximum and IQR (interquartile range), by study (MVX0002, MVX0003) and dose level received in the MVX0002 study (placebo/vaccine naïve, 25ug, 50ug) and active doses pooled.

For study MVX0002, treatment groups will be presented as:

- Placebo
- 25 µg GBS-NN/NN2
- 50 µg GBS-NN/NN2
- GBS-NN/NN2 Overall

For the current study MVX0003, treatment groups will be presented in relation to the treatment previously received in the MVX0002 study as:

- MVX0002 Placebo/Vaccine-naïve
- MVX0002 25 µg GBS-NN/NN2)
- (MVX0002 50 µg GBS-NN/NN2)
- (MVX0002 GBS-NN/NN2 Overall
- Overall

Individual IgG antibody concentrations (specific for GBS-NN and GBS-NN2) over time will be presented graphically on a linear scale with one plot per subject presenting results of both the MVX0002 and MVX0003 studies, where applicable. Geometric mean (and 95% CI) plots of antibody concentrations will also be produced by study (MVX0002, MVX0003) and dose level received in the MVX0002 study (placebo/vaccine naïve, 25 µg, 50 µg), active doses pooled and overall.

In order to explore the decline in IgG antibodies since the previous study, a statistical comparison of the GBS-NN and GBS-NN2 antibody concentrations on Day 1 of the MVX0003 study and Day 85 of the MVX0002 study will be performed for each of the corresponding MVX0002 dose levels and active doses pooled only for subjects who participated in both studies. Following logarithmic transformation, antibody concentrations will be subjected to a mixed effect analysis of variance (ANOVA), with study as a fixed

effect and subject as a random effect. Point estimates and 95% confidence intervals will be constructed for the contrasts between Day 1 (MVX0003) and Day 85 (MVX0002). The point and interval estimates will be back-transformed to give estimates of the ratios of the geometric least squares means (LSMeans) and corresponding 95% CIs for each MVX0002 dose level and all active doses pooled.

A similar ANOVA will also be performed in order to compare the Day 85 GBS-NN and GBS-NN2 antibody concentrations for the MVX0003 study to those obtained for the MVX0002 study, for each of the corresponding MVX0002 dose levels and all active doses pooled.

Additionally, the GBS-NN and GBS-NN2 antibody concentrations observed on Day 85 of the MVX0003 study will be compared between subjects who received 25 µg GBS-NN/GBS-NN2 in the previous study and placebo/vaccine-naïve subjects, between subjects who received 50 µg GBS-NN/ NN2 in the previous study and between placebo/vaccine-naïve subjects and the subjects who received either active dose (25 µg and 50 µg pooled) in the previous study and placebo/vaccine-naïve subjects. Following logarithmic transformation, Day 85 antibody concentrations will be subjected to an analysis of variance (ANOVA), with dose level as a fixed effect. Point estimates and 95% CIs will be constructed for the contrasts between the dose levels. The point and interval estimates will be back-transformed to give estimates of the ratios of the geometric LSMeans and corresponding 95% CIs.

The fold-increase in antibody concentrations specific for GBS-NN and GBS-NN2 will be derived between:

- Day 1 and Day 85 (i.e. Day 85 concentration / Day 1 concentration) for both the MVX0002 and MVX0003 studies, for each of the corresponding MVX0002 dose levels and all active vaccines pooled.
- Day 85 of the MVX0002 study and Day 85 of the of the current MVX0003 study (i.e. Day 85 MVX0003 / Day 85 MVX0002), for each of the corresponding MVX0002 dose levels and all active vaccines pooled.

Fold-increases will be listed and descriptive statistics (N, n, geometric mean and corresponding 95% CI, minimum, median, maximum and IQR) will be tabulated by study and MVX0002 dose level and all active vaccines pooled.

In addition, the proportion of subjects with concentrations above the pre-determined thresholds of 1, 2, 4 and 8 µg/mL at Day 85 will be presented by study and MVX0002 dose level and all active vaccines pooled using N, n and % This will provide an assessment of the immune response to dose.

Antibody response data will be listed using the Safety Set. Summary tables and figures and statistical analyses will be performed primarily using the IG Set and optionally repeated using the PP Set, should the number of subjects included in the PP Set differ by more than 5% from the IG set.

11.5.2 Specific Antibody concentration Data

Individual subject antibody concentration specific for AlpCN, RibN, Alp1N and Alp2-3N will be analysed and reported separately, therefore it is not included in the scope of this document

11.5.3 [redacted] Data

Additional exploratory assessments for exploratory objectives including [redacted] results will be analysed and reported separately, therefore it is not included in the scope of this document.

11.6 SAFETY ANALYSES

11.6.1 Adverse Events

All adverse events (AEs) will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary version 24.0.

All AEs will be listed, two separate listings will be produced, one for Treatment Emergent Adverse Events (TEAEs) and one for Non-Treatment Emergent Adverse Events (NTEAEs). An adverse event will be regarded as an NTEAE if it stops prior to administration of first treatment. The treatment phase will be presented as 'Prior to Treatment'. For an NTEAE that started prior to first administration of study drug but is ongoing following administration of first treatment, the treatment phase will be described as 'Prior and Ongoing'. Otherwise, the AE will be defined as treatment emergent and assigned to the treatment the AE started on.

Only TEAEs, i.e., existing conditions that worsen or events that occur during the course of the study after administration of IMP, up to and including Day 85, will be included within the summary tables. NTEAEs are defined as events that occur before the first study vaccine administration. AEs that occur intermittently will be reported as separate events.

An AE will be assigned to treatment if it starts on or after dosing. Where there are only partial dates/times recorded for an adverse event, the adverse event will be assigned to treatment if it cannot be ruled out based on the partial information.

An overall summary of AEs will be produced including the number of TEAEs; the number and % of subjects reporting at least 1 TEAE, serious TEAE (where SAE is reported as 'Yes'), TEAE leading to withdrawal from the study (Action recorded as 'Drug Withdrawn'); TEAE leading to death (Outcome recorded as 'Fatal'); the number and % of subjects reporting TEAEs by severity and relationship to IMP. A subject with multiple occurrences of any AE is counted only once at the maximum level of severity and the highest association to study drug.

The number of TEAEs and the number and % of subjects reporting at least 1 TEAE will be tabulated by system organ class (SOC) and preferred term (PT). A subject reporting multiple episodes of a particular AE within a treatment period will only contribute 1 count towards the corresponding SOC and PT.

In order to highlight the most frequently reported TEAEs, the number of TEAEs and the number and % of subjects reporting at least 1 TEAE will be tabulated by PT in order of descending frequency such that AEs reported by the greatest number of subjects are presented first. A subject reporting multiple episodes of a particular AE will only contribute 1 count towards the corresponding PT.

In addition, the number and % of subjects reporting TEAEs will be tabulated by maximum severity and strongest relationship to study drug. For the summary of TEAEs by severity, if a subject has multiple events occurring within the same SOC or PT the event with the highest severity will be counted. Similarly, for TEAEs by relationship to study drug, if a subject has multiple events occurring within the same SOC or PT, the event with the strongest relationship to study drug will be counted.

The derived variables, 'Time from Dose' and 'Duration' will be presented where full date and time are present. If partial dates are present for any parameter required in the calculation, the variable will not be populated. The following will be used to calculate the variables:

Duration (dd:hh:mm): (Date/Time of Resolution – Date/Time of Onset) + 1 minute

Time from Dose (dd:hh:mm): (Date/Time of Onset – Date/Time of Start of Dose)

The following will be presented in listing format within the data summaries:

- Serious Adverse Events – If there are none present, the listing will be produced stating: '*No subjects experienced any serious adverse events.*'.
- Adverse Events which Led to Withdrawal – If there are none present, the listing will be produced stating: '*No subjects experienced any adverse events that led to withdrawal.*'.
- Adverse Events Leading to Death – If there are none present, the listing will be produced stating: '*No subjects experienced any adverse events that led to death.*'.

Adverse event data will be listed and summarised using the Safety Set.

In the case of few TEAEs (≤5), only listings will be created.

11.6.2 Systemic Reactogenicity

Systemic reactogenicity AEs will be categorised using the MedDRA preferred term. Systemic reactogenicity AEs are defined as:

- Headache
- Fatigue
- Myalgia (non-injection site)
- Fever
- Chills
- Arthralgia
- Flu-like symptoms
- Rash

Any adverse event as listed above will only be considered a systemic reactogenicity effect if they occur within 72 h post-IMP administration. Outside of this timeframe, the events are considered AEs but not signs or symptoms of systemic reactogenicity to the IMP.

The previously specified AE summaries in section 11.6.1 will be additionally produced on the subset of systemic reactogenicity AEs.

11.6.3 Local Reactogenicity

Local reactogenicity AEs will be identified as those which have a MedDRA Higher Level Term (HLT) of INJECTION SITE REACTIONS.

An adverse event will only be considered a local reactogenicity effect if it has an onset within 72 h post-IMP administration. Outside of this timeframe, the events are considered AEs but not signs or symptoms of local reactogenicity to the IMP.

Local reactogenicity AEs will be listed and a summary by severity will be produced. A subject with multiple occurrences of any AE is counted only once at the maximum level of severity.

For the local reactogenicity AE symptoms of pain, redness, bruising, tenderness, swelling and itching, the number of events and the number and % of subjects reporting at least 1 occurrence of the aforementioned symptoms will be tabulated. A subject reporting multiple episodes of a particular symptom will only contribute 1 count.

11.6.4 Autoimmune Diseases and Clinically Relevant Events

Any adverse events occurring within the 6-month (up to Day 183) follow-up period which are considered to be indicative of auto-immune disease or clinically relevant will be presented separately using the Safety Set.

11.6.5 Significant Adverse Drug Reactions Post Day 85

In order to identify significant adverse drug reactions, a listing of adverse events occurring after Day 85 will be provided. This listing will be used along with any additionally available information to identify significant adverse drug reactions.

Adverse event data after Day 85 will be listed by treatment using the Safety Set.

11.6.6 Laboratory Data

Routine safety clinical laboratory tests (biochemistry and hematology) will be carried out at: Screening, Day 8, Day 29, Day 57 and Day 183. In addition, samples for urinalysis will be taken at Screening and Day 183.

The laboratory parameters required for this study are listed in section 9.2.1.

Laboratory data listings will be presented in two ways:

- Out of range values – any values that fall outside of the normal/alert ranges based on the reference ranges provided by the central laboratory (presented in listing format within the data summaries)
- All safety laboratory data (including physician's review (Normal, Abnormal-NCS, Abnormal-CS)) with any out of range values flagged (presented within the data listings).

Descriptive statistics (N, n, mean, SD, minimum, median and maximum) of absolute and change from baseline (Screening) values for each biochemistry and hematology parameter at each timepoint, up to and including Day 183, will be tabulated.

Microscopy, virology, COVID-19 RT-PCR test, urine drugs of abuse and alcohol screen, pregnancy test, post-menopausal assessment and any unplanned laboratory parameters will also be listed.

If there are no further parameters databased other than those specified in section 9.2.1 then the 'Other Laboratory Data' listings should display, 'No other laboratory parameters to report'.

Laboratory data will be listed and summarised using the Safety Set.

11.6.7 Vital Signs

Vital Signs will be recorded at: Screening, Day 1 (pre-dose and 30 min (±5 min) post dose), Day 8, Day 29, Day 57, Day 85 and Day 183.

Vital signs parameters (supine systolic/diastolic blood pressure, heart rate, tympanic temperature and respiration rate) will be listed with any out of normal range values (see Appendix 16.1) flagged (flag appended to relevant result). Descriptive statistics (N, n, mean, SD, minimum, median and maximum) of absolute and change from baseline (Day 1 pre-dose) values at each timepoint, up to and including Day 183, will be tabulated.

Vitals signs data will be listed and summarised using the Safety Set.

11.6.8 Electrocardiogram

12-lead ECG will be performed at Screening only. 12-lead ECG parameters (heart rate, PR interval, QRS width, QT interval and QT interval corrected using Fredericia's formula (QTcF)) will be listed with any out of normal range values (see Appendix 16.1) flagged (flag appended to relevant result), using the Safety Set.

11.6.9 Injection Site Reactions

Injection Site Reaction assessments of redness, bruising, induration, itching and pain will be conducted at pre-dose and 30 min (±5 min) post dose on Day 1, Day 8, Day 29, Day 57, and Day 85.

Injection Site Reaction assessments will be listed and summarised using the Safety Set.

11.6.10 Physical Examination

Full physical examination will be performed at Screening. A brief physical examination will be performed pre-dose on Day 1 and a Symptom-Directed Physical Examination (SDPE) will be performed prior to discharge at 30 min (±5 min) post-dose on Day 1. Brief physical examinations will also be conducted on Day 8, Day 29 and at the safety follow up visit (Day 183).

A physical examination will be performed by an Investigator and will include ear/nose/throat, ophthalmological, dermatological, cardiovascular, respiratory, gastrointestinal, central nervous system, lymph nodes and musculoskeletal.

Physical examination results will be listed using the Safety Set.

11.7 OTHER

11.7.1 Prior and Concomitant Medication

A medication will be assigned to treatment if it starts on or after dosing. Where there are only partial dates/times recorded for a medication, the medication will be assigned to treatment if it cannot be ruled out based on the partial information.

A medication will be regarded as *prior* if it stops prior to first administration of IMP. The treatment phase will be presented as 'Prior to Treatment'. A medication will be regarded as *concomitant* if it starts after dosing or starts before dosing and continues after dosing. For any medication that started prior to first administration of IMP but is ongoing following administration of IMP, the treatment phase will be described as 'Prior and Ongoing'. Otherwise, treatment phase will be described as the treatment the medication started on.

Prior and concomitant medications will be listed using the Safety Set.

11.8 ALL OTHER DATA

All data will be listed using the Safety Set, including the following: Visit Dates, Substance Use History, Obstetric History, Inclusion/Exclusion Failures, Dose Administration, PD Sampling Information for Antibody Response, Exploratory [redacted] Sampling Information, Blood Sample for Future Work Information, Diary Card Completion and Additional Comments will be listed by subject.

Derivations within listings:

Analysis sets: Detail whether subject should be included within each of the analysis sets and provide reason for exclusion, as appropriate.

Inclusion/Exclusion criteria: Only failures to be presented. If there are no failures display '*All subjects passed all inclusion/exclusion criteria.*'

Protocol deviations: Major/minor classification to be assigned and confirmed by Sponsor.

12 VALIDATION

All tables, figures and listings will be subject to independent quality control and visual review and will be independently programmed. Findings will be documented in an Output Summary file quality control form and actions taken will also be documented.

The study summary sheet of the Output Summary file will be completed and signed by all persons who performed programming and QC. The final signed version of the Output Summary will be stored in the Trial Master File (TMF).

13 LITERATURE CITATIONS/REFERENCES

None.

14 LIST OF TABLES, FIGURES AND LISTINGS

List of Tables and Figures Contained in Report Section 14

14.1 Disposition and Demographic Data

14.1.1 Disposition Data

Table 14.1.1.1	Summary of Study Disposition	All Consented Set

14.1.2 Demographic Data and Baseline Characteristics

Table 14.1.2.1	Summary of Demographic Information	Safety Set
Table 14.1.2.2	Summary of Medical History by System Organ Class and Preferred Term	Safety Set

14.2 Efficacy Data

Not applicable.

14.3 Safety Data

14.3.1 Adverse Events

Table 14.3.1.1	Summary of Treatment Emergent Adverse Events up to Day 85	Safety Set
Table 14.3.1.2	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term up to Day 85	Safety Set
Table 14.3.1.3	Summary of Treatment Emergent Adverse Events by Preferred Term up to Day 85	Safety Set
Table 14.3.1.4	Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Severity up to Day 85	Safety Set
Table 14.3.1.5	Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Relationship up to Day 85	Safety Set
Table 14.3.1.6	Serious Adverse Events up to Day 85	Safety Set
Table 14.3.1.7	Adverse Events Leading to Withdrawal up to Day 85	Safety Set
Table 14.3.1.8	Adverse Events Leading to Death up to Day 85	Safety Set
Table 14.3.1.9	Summary of Systemic Reactogenicity Adverse Events occurring within 72h of IMP	Safety Set
Table 14.3.1.10	Summary of Systemic Reactogenicity Adverse Events by System Organ Class and Preferred Term occurring within 72h of IMP	Safety Set
Table 14.3.1.11	Summary of Systemic Reactogenicity Adverse Events by Preferred Term occurring within 72h of IMP	Safety Set

14.3.1 Adverse Events

Table 14.3.1.12	Summary of Systemic Reactogenicity Adverse Events by System Organ Class, Preferred Term and Severity occurring within 72h of IMP	Safety Set
Table 14.3.1.13	Summary of Systemic Reactogenicity Adverse Events by System Organ Class, Preferred Term and Relationship occurring within 72h of IMP	Safety Set
Table 14.3.1.14	Summary of Local Reactogenicity Adverse Events occurring within 72h of IMP by Severity	Safety Set
Table 14.3.1.15	Summary of Local Reactogenicity Adverse Event Symptoms occurring within 72h of IMP	Safety Set
Table 14.3.1.16	Autoimmune Diseases and Clinically Relevant Treatment Emergent Adverse Events Occurring within 6 months of IMP	Safety Set

14.3.2 Laboratory Safety

Table 14.3.2.1	Biochemistry Out of Normal Range Data	Safety Set
Table 14.3.2.2	Hematology Out of Normal Range Data	Safety Set
Table 14.3.2.3	Urinalysis Out of Normal Range Data	Safety Set
Table 14.3.2.4	Summary of Absolute and Change from Baseline Biochemistry Data	Safety Set
Table 14.3.2.5	Summary of Absolute and Change from Baseline Hematology Data	Safety Set

14.3.3 Vital Signs

Table 14.3.3.1	Summary of Absolute and Change from Baseline Vital Signs Data	Safety Set

14.4 Pharmacokinetics

Not applicable.

14.5 Pharmacodynamics

14.5.1 Immunogenicity

Table 14.5.1.1	Summary of IgG Antibody Concentrations	IG Set
Figure 14.5.1.1	Geometric Mean IgG Antibody Concentrations	IG Set
Table 14.5.1.2	Statistical Comparison of IgG Antibody Concentrations - Day 1 (MVX0003) vs Day 85 (MVX0002)	IG Set
Table 14.5.1.3	Statistical Comparison of Day 85 IgG Antibody Concentrations – MVX0003 vs MVX0002	IG Set

Table 14.5.1.4	Statistical Comparison of MVX0003 Day 85 IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects	IG Set
Table 14.5.1.5	Summary of Fold-Increase in IgG Antibody Concentrations from Day 1 to Day 85	IG Set
Table 14.5.1.6	Summary of Fold-Increase in IgG Antibody Concentrations from Day 85 MVX0002 to Day 85 MVX0003	IG Set
Table 14.5.1.7	Summary of Immune Response at Day 85 – Proportion above Threshold	IG Set
Table 14.5.1.8	Summary of IgG Antibody Concentrations – (*if required*)	PP Set
Figure 14.5.1.2	Geometric Mean IgG Antibody Concentrations - (*if required*)	PP Set
Table 14.5.1.9	Statistical Comparison of IgG Antibody Concentrations - Day 1 (MVX0003) vs Day 85 (MVX0002) – (*if required*)	PP Set
Table 14.5.1.10	Statistical Comparison of Day 85 IgG Antibody Concentrations – MVX0003 vs MVX0002 – (*if required*)	PP Set
Table 14.5.1.11	Statistical Comparison of MVX0003 Day 85 IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects – (*if required*)	PP Set
Table 14.5.1.12	Summary of Fold-Increase in IgG Antibody Concentrations from Day 1 to Day 85 – (*if required*)	PP Set
Table 14.5.1.13	Summary of Fold-Increase in IgG Antibody Concentrations from Day 85 MVX0002 to Day 85 MVX0003 – (*if required*)	PP Set
Table 14.5.1.14	Summary of Immune Response at Day 85 – Proportion above Threshold - (*if required*)	PP Set

Subject Data: Listings Contained in Report Appendix 16.2

16.2.1 Visit Dates, Dosing Information and Disposition

Listing 16.2.1.1	Visit Dates	Safety Set
Listing 16.2.1.2	Dose Administration	Safety Set
Listing 16.2.1.3	Subject Disposition	All Consented Set
Listing 16.2.1.4	Additional Comments	Safety Set

16.2.2 Protocol Deviations

Listing 16.2.2.1	Protocol Deviations	Safety Set

16.2.3 Analysis Sets

Listing 16.2.3.1	Analysis Sets	All Consented Set

16.2.4 Demographic Data and Other Baseline Characteristics

Listing 16.2.4.1	Demographic Information	Safety Set
Listing 16.2.4.2	Medical History and Concurrent Conditions	Safety Set
Listing 16.2.4.3	Virology Test Results	Safety Set
Listing 16.2.4.4	COVID-19 Test Results	Safety Set
Listing 16.2.4.5	Drugs of Abuse Results	Safety Set
Listing 16.2.4.6	Obstetric History	Safety Set
Listing 16.2.4.7	Pregnancy Test Results	Safety Set
Listing 16.2.4.8	Post-Menopausal Assessment	Safety Set
Listing 16.2.4.9	Substance Use History	Safety Set
Listing 16.2.4.10	Inclusion/Exclusion Criteria Failures	Safety Set

16.2.5 Drug Concentration Data and Pharmacokinetics

Not applicable.

16.2.6 Efficacy

Not applicable.

16.2.7 Adverse Events

Listing 16.2.7.1	Non-Treatment Emergent Adverse Events	Safety Set
Listing 16.2.7.2	Treatment Emergent Adverse Events	Safety Set
Listing 16.2.7.3	Systemic Reactogenicity Adverse Events Occurring within 72h of IMP	Safety Set
Listing 16.2.7.4	Local Reactogenicity Adverse Events Occurring within 72h of IMP	Safety Set
Listing 16.2.7.5	Adverse Events after Day 85	Safety Set

16.2.8 Individual Laboratory Safety Measurements

Listing 16.2.8.1	Biochemistry Data	Safety Set
Listing 16.2.8.2	Hematology Data	Safety Set
Listing 16.2.8.3	Urinalysis Data	Safety Set
Listing 16.2.8.4	Microscopy Data	Safety Set
Listing 16.2.8.5	Other Laboratory Data	Safety Set

16.2.9 Vital Signs

Listing 16.2.9.1	Vital Signs Data	Safety Set

16.2.10 Physical Examination

Listing 16.2.10.1	Physical Examination Data	Safety Set

16.2.11 ECG

Listing 16.2.11.1	12-lead ECG Data	Safety Set

16.2.12 Prior and Concomitant Medication

Listing 16.2.12.1	Prior and Concomitant Medications	Safety Set

16.2.13 Injection Site Reaction

Listing 16.2.13.1	Injection Site Reaction Assessments	Safety Set

16.2.14 Immunogenicity

Listing 16.2.14.1	IgG Antibody Concentration and Fold Increase Data	Safety Set
Figure 16.2.14.1	Individual IgG Antibody Concentrations	Safety Set
Listing 16.2.14.2	Raw Statistical Analysis of IgG Antibody Concentrations - Day 1 (MVX0003) vs Day 85 (MVX0002)	IG Set
Listing 16.2.14.3	Raw Statistical Analysis of IgG Antibody Concentrations for Day 85 – MVX0003 vs MVX0002	IG Set
Listing 16.2.14.4	Raw Statistical Analysis of IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects	IG Set
Listing 16.2.14.5	Raw Statistical Analysis of IgG Antibody Concentrations - Day 1 (MVX0003) vs Day 85 (MVX0002) – (*if required*)	PP Set
Listing 16.2.14.6	Raw Statistical Analysis of IgG Antibody Concentrations for Day 85 – MVX0003 vs MVX0002 – (*if required*)	PP Set
Listing 16.2.14.7	Raw Statistical Analysis of IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects – *(if required)*	PP Set

16.2.15 Other Data

Listing 16.2.15.1	Diary Card Completion	Safety Set
Listing 16.2.15.2	PD Sampling Information for Antibody Response	Safety Set
Listing 16.2.15.3	Exploratory [redacted] Sampling Information	Safety Set
Listing 16.2.15.4	Blood Sample for Future Work Information	Safety Set

15 SHELLS FOR TABLES, FIGURES AND LISTINGS

The intended layouts for tables, figures and listings are presented. However, it may be appropriate to change the layouts, upon review of the data available, for completeness and clarity.

QCd output will be produced as Rich Text Format (.rtf) files for convenient inclusion in the CSR.
The default tables, figures and listings (TFL) layout will be as follows:

Orientation	A4 Landscape
Margins	Top: 2.54 cm Bottom: 2.54 cm Left: 2.54 cm Right: 2.54 cm
Font	Courier New 9pt
Headers (Centre)	Sponsor Protocol Number, TFL Number, Title, Analysis Set
Footers (Left)	Source Listing, Date/Time TFL Generated, Page Number, i.e. Page x of y

Listing shells are displayed within this document without the comments field but, should there be any comments recorded for the represented data, this field will be added to the listing. In addition, at the time of programming, footnotes will be added to the listing, table or figure as needed. All footnotes will be used for purposes of clarifying the presentation.

Should the number of variables within a listing or table be too great to fit on one page without compromising clarity, then the variables will be split across multiple subsequent pages and key identifying variables replicated with these (i.e. subject number, visit etc). The differing pages will be identified using a sequential number which will follow the TFL title, i.e. xxxx - (1), xxxx - (2).

All final TFLs will be reported from SDTM and ADaM datasets. SDTM and ADaM details will be documented in a separate specification document.

MVX0003
Table 14.1.1.1
Summary of Study Disposition
All Consented Set

	Overall (N=X)
Screened	x
Screening Failures/Non-Runners	x
Dosed MVX0003 50 µg GBS-NN/NN2	x (x.x)
Vaccine Naïve	x (x.x)
MVX0002 Placebo	x (x.x)
MVX0002 25 µg GBS-NN/NN2	x (x.x)
MVX0002 50 µg GBS-NN/NN2	x (x.x)
Completed Study	x (x.x)
Study Termination	x (x.x)
Reason for Study Termination	
ADVERSE EVENT	x (x.x)
LOST TO FOLLOW-UP	x (x.x)
WITHDRAWAL BY SUBJECT	x (x.x)
STUDY TERMINATED BY SPONSOR	x (x.x)
PHYSICIAN DECISION	x (x.x)
PROTOCOL VIOLATION	x (x.x)
DEATH	x (x.x)
OTHER	x (x.x)
All Consented Set	x (x.x)
Safety Set	x (x.x)
Immunogenicity Set	x (x.x)
Per Protocol Set	x (x.x)

Source Listing: 16.2.1.2, 16.2.1.3, 16.2.3.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Percentages calculated from the number of subjects dosed.

MVX0003
Table 14.1.2.1
Summary of Demographic Information
Safety Set

Parameter	Statistic	MVX0002 Placebo/ Vaccine Naïve	MVX0002 25 µg GBS-NN/NN2 (N=x)	MVX0002 50 µg GBS-NN/NN2 (N=x)	GBS-NN/NN2 Overall (N=x)	Overall (N=x)
Age (yrs)	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx	x.xx	x.xx
	Min	x	x	x	x	x
	Median	x.x	x.x	x.x	x.x	x.x
	Max	x	x	x	x	x
Height (m)	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx	x.xx	x.xx
	Min	x	x	x	x	x
	Median	x.x	x.x	x.x	x.x	x.x
	Max	x	x	x	x	x
Weight (kg)	n	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx	x.xx	x.xx
	Min	x	x	x	x	x
	Median	x.x	x.x	x.x	x.x	x.x
	Max	x	x	x	x	x

Source Listing: 16.2.4.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Percentages will be calculated from the number of subjects in the Safety Set within a treatment group.

MVX0003
Table 14.1.2.1
Summary of Demographic Information
Safety Set

Parameter		Statistic	MVX0002 Placebo/ Vaccine Naïve	MVX0002 25 µg GBS-NN/NN2 (N=x)	MVX0002 50 µg GBS-NN/NN2 (N=x)	GBS-NN/NN2 Overall (N=x)	Overall (N=x)
BMI (kg/m^2)		n	x	x	x	x	x
		Mean	x.x	x.x	x.x	x.x	x.x
		SD	x.xx	x.xx	x.xx	x.xx	x.xx
		Min	x	x	x	x	x
		Median	x.x	x.x	x.x	x.x	x.x
		Max	x	x	x	x	x
Ethnic Group	NOT HISPANIC OR LATINO	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	HISPANIC OR LATINO	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	NOT REPORTED	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	UNKNOWN	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Race	BLACK OR AFRICAN AMERICAN	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	AMERICAN INDIAN OR ALASKA NATIVE	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	ASIAN	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	WHITE	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	MIXED	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	OTHER	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source Listing: 16.2.4.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Percentages will be calculated from the number of subjects in the Safety Set within a treatment group.

MVX0003
Table 14.1.2.2
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

	Number (%) of Subjects				
System Organ Class Preferred Term	MVX0002 Placebo/ Vaccine Naïve	MVX0002 25 µg GBS-NN/NN2 (N=x)	MVX0002 50 µg GBS-NN/NN2 (N=x)	GBS-NN/NN2 Overall (N=x)	Overall (N=X)
<SYSTEM ORGAN CLASS>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<SYSTEM ORGAN CLASS>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<PREFERRED TERM>	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source Listing: 16.2.4.2; Produced: yyyy-mm-ddThh:mm - Page x of y
A subject is counted only once per system organ class and preferred term within each treatment category.
Percentages will be calculated from the number of subjects in the Safety Set within a treatment group.

MVX0003
Table 14.3.1.1
Summary of Treatment Emergent Adverse Events up to Day 85
Safety Set

	MVX0003 50 µg GBS-NN/NN2 (N=X)
Number of TEAEs	x
Number (%) of subjects reporting at least one:	
TEAE	x (x.x)
Serious TEAE	x (x.x)
TEAE Leading to Withdrawal	x (x.x)
Number (%) of subjects with TEAE by severity:	
MILD	x (x.x)
MODERATE	x (x.x)
SEVERE	x (x.x)
Number (%) of subjects with TEAE by relationship to study drug:	
REASONABLE POSSIBILITY	x (x.x)
NO REASONABLE POSSIBILITY	x (x.x)

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject with multiple adverse events is counted only once at the maximum level of severity or the highest association to treatment.

Programming Note: Similar tables will be produced for:
Table 14.3.1.9 Summary of Systemic Reactogenicity Adverse Events occurring within 72h of IMP.

MVX0003
Table 14.3.1.2
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term up to Day 85
Safety Set

System Organ Class Preferred Term	Number of Events / Number (%) of Subjects MVX0003 50 µg GBS-NN/NN2 (N=X)
<SYSTEM ORGAN CLASS>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<SYSTEM ORGAN CLASS>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject is counted only once per System Organ Class and Preferred Term.
Percentages calculated from the number of subjects in the Safety Set.

Programming Note: Similar tables will be produced for:
Table 14.3.1.10 Summary of Systemic Reactogenicity Adverse Events by System Organ Class and Preferred Term occurring within 72h of IMP.

MVX0003
Table 14.3.1.3
Summary of Treatment Emergent Adverse Events by Preferred Term up to Day 85
Safety Set

Preferred Term	Number of Events / Number (%) of Subjects MVX0003 50 µg GBS-NN/NN2 (N=X)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)
<PREFERRED TERM>	x / x (x.x)

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject is counted only once per Preferred Term.
Percentages calculated from the number of subjects in the Safety Set.

Programming Note: To be sorted in descending frequency of number of subjects.
Programming Note: Similar tables will be produced for:
Table 14.3.1.11 Summary of Systemic Reactogenicity Adverse Events by Preferred Term occurring within 72h of IMP.

MVX0003
Table 14.3.1.4
Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Severity up to Day 85
Safety Set

System Organ Class Preferred Term	Severity	Number (%) of Subjects MVX0003 50 µg GBS-NN/NN2 (N=X)
<SYSTEM ORGAN CLASS>	MILD	x (x.x)
	MODERATE	x (x.x)
	SEVERE	x (x.x)
<PREFERRED TERM>	MILD	x (x.x)
<PREFERRED TERM>	MILD	x (x.x)
<PREFERRED TERM>	MILD	x (x.x)
	MODERATE	x (x.x)
	SEVERE	x (x.x)

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject with multiple occurrences of an AE is counted only once at the maximum level of severity within that System Organ Class and Preferred Term.
Percentages calculated from the number of subjects in the Safety Set.

Programming Note: Similar tables will be produced for:
Table 14.3.1.12 Summary of Systemic Reactogenicity Adverse Events by System Organ Class, Preferred Term and Severity occurring within 72h of IMP.

MVX0003
Table 14.3.1.5
Summary of Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Relationship up to Day 85
Safety Set

		Number (%) of Subjects
System Organ Class Preferred Term	Relationship to Study Drug	MVX0003 50 µg GBS-NN/NN2 (N=X)
<SYSTEM ORGAN CLASS>	REASONABLE POSSIBILITY	x (x.x)
		x (x.x)
<PREFERRED TERM>	REASONABLE POSSIBILITY	x (x.x)
<PREFERRED TERM>	NO REASONABLE POSSIBILITY	x (x.x)
<PREFERRED TERM>	REASONABLE POSSIBILITY	x (x.x)

Source Listing: 16.2.7.2; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject with multiple occurrences of an AE is counted only once at the highest association to study drug within that System Organ Class and Preferred Term.
Percentages calculated from the number of subjects in the Safety Set.

Programming Note: Similar tables will be produced for:
Table 14.3.1.13 Summary of Systemic Reactogenicity Adverse Events by System Organ Class, Preferred Term and Relationship occurring within 72h of IMP.

MVX0003
Table 14.3.1.6
Serious Adverse Events up to Day 85 - (1)
Safety Set

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Start Date/ Time	End Date/ Time/Ongoing	Duration (dd:hh:mm)	Time from Dose (dd:hh:mm)	Date Reported
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx
xxx	x	xx/xx/xx	xxxxxTxx:xx	xxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxxxxTxx:xx

Source Listing: 16.2.7.1; Produced: yyyy-mm-ddThh:mm - Page x of y
SAE = Serious Adverse Event.

Programming Note: A similar tables will be produced for:
Table 14.3.1.7 Adverse Events Leading to Withdrawal up to Day 85.
Table 14.3.1.8 Adverse Events Leading to Death up to Day 85.
Table 14.3.1.16 Autoimmune Diseases and Clinically Relevant Treatment Emergent Adverse Events occurring within 6 months of IMP.

MVX0003
Table 14.3.1.6
Serious Adverse Events up to Day 85 - (2)
Safety Set

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Severity	Relationship	Action	Outcome	SAE	Systemic Reactogenicity Events	SAE Criteria	Comments
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	xxxxxxxx
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	
xxx	x	xx/xx/xx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxxx	

Source Listing: 16.2.7.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.

Programming Note: A similar tables will be produced for:
Table 14.3.1.7 Adverse Events Leading to Withdrawal up to Day 85.
Table 14.3.1.8 Adverse Events Leading to Death up to Day 85.
Table 14.3.1.16 Autoimmune Diseases and Clinically Relevant Treatment Emergent Adverse Events occurring within 6 months of IMP.

MVX0003
Table 14.3.1.14
Summary of Local Reactogenicity Adverse Events occurring within 72h of IMP by Severity
Safety Set

	MVX0003 50 µg GBS-NN/NN2 (N=X)
Number of Injection Site Reactions	x
Number (%) of subjects reporting at least one Injection Site Reaction:	x (x.x)
Number (%) of subjects with Injection Site Reaction by severity:	
MILD	x (x.x)
MODERATE	x (x.x)
SEVERE	x (x.x)

Source Listing: 16.2.7.4; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
A subject with multiple adverse events is counted only once at the maximum level of severity.
Percentages calculated from the number of subjects in the Safety Set.

MVX0003
Table 14.3.4.15
Summary of Local Reactogenicity Adverse Event Symptoms occurring within 72h of IMP
Safety Set

	Number (%) of Subjects
Symptom	MVX0003 50 µg GBS-NN/NN2 (N=X)
PAIN	x (x.x)
REDNESS	x (x.x)
BRUISING	x (x.x)
TENDERNESS	x (x.x)
ITCHING	x (x.x)
SWELLING	x (x.x)

Source Listing: 16.2.7.4; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Percentages calculated from the number of subjects in the Safety Set.

MVX0003
Table 14.3.2.1
Biochemistry Out of Normal Range Data
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Parameter (Unit)	Result	Flag	Normal Range Low	Normal Range High	Alert Range Low	Alert Range High
xxx	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)						
	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
H* = Above Alert Range; H = Above Normal Range; Lo= Below Normal Range; L* = Below Alert Range.

MVX0003
Table 14.3.2.2
Haematology Out of Normal Range Data
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Parameter (Unit)	Result	Flag	Normal Range Low	Normal Range High	Alert Range Low	Alert Range High
xxx	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx

Source Listing: 16.2.8.2; Produced: yyyy-mm-ddThh:mm - Page x of y
H* = Above Alert Range; H = Above Normal Range; Lo = Below Normal Range; L* = Below Alert Range.

MVX0003
Table 14.3.2.3
Urinalysis Out of Normal Range Data
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Parameter (Unit)	Result	Flag	Normal Range Low	Normal Range High
xxx	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxx(xxx)	x.xx	x	x.x	x.xx

Source Listing: 16.2.8.3; Produced: yyyy-mm-ddThh:mm - Page x of y
H = Above Normal Range; Lo = Below Normal Range.

MVX0003
Table 14.3.2.4
Summary of Absolute and Change from Baseline Biochemistry Results
Safety Set

<Parameter (UNITS)>

	Absolute						Change from Baseline					
Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x

Source Listing: 16.2.8.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Baseline defined as the last available pre-dose value.

Programming Note: Table will be replicated within an output for each planned parameter. A similar table will be produced for Table 14.3.2.5 Summary of Absolute and Change from Baseline Hematology Data.

MVX0003
Table 14.3.3.1
Summary of Absolute and Change from Baseline Vital Signs Data
Safety Set

<Parameter (UNITS)>

Visit/ Time Point	Absolute						Change from Baseline					
	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x						
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x
<VISIT>	x	x.xx	x.xxx	x.x	x.xx	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x

Source Listing: 16.2.9.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Baseline defined as the last available pre-dose value.

Programming Note: Table will be replicated within an output for each planned parameter.

MVX0003
Table 14.5.1.1
Summary of IgG Antibody Concentrations
Immunogenicity Set

<STUDY> - *<Antigen (units)>*

		Absolute								Change from Baseline						
Treatment Group	Study Day	n	Mean	SD	Geo. Mean (95% CI)	Min	Median	Max	IQR	n	Mean	SD	Min	Median	Max	IQR
<Treatment> (N=X)	DAY 1	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x							
	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x	x.x
<Treatment> (N=X)	DAY 1	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x							
	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x	x.x
<Treatment> (N=X)	DAY 1	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x							
	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x	x	x.xx	x.xxx	x.x	x.xx	x.x	x.x

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
MVX0003 treatment groups defined in relation to the corresponding treatment received by each subject in the MVX0002 study.
Baseline defined as Day 1.
Lower Limit of Quantification = xx.xx *<units>*. Results reported as <LLOQ were imputed as LLOQ/2.

Programming Note: For study MVX0002, treatments to be presented as Placebo, 25 µg GBS-NN/NN2, 50 µg GBS-NN/NN2 and GBS-NN/NN2 Overall. For study MVX0003, MVX0002 Placebo/Vaccine-Naïve, MVX0002 25 µg GBS-NN/NN2, MVX0002 50 µg GBS-NN/NN2, MVX0002 GBS-NN/NN2 Overall and Overall.

Programming Note: A similar table will be produced for Table 14.5.1.8 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Figure 14.5.1.1
Geometric Mean and 95% CI IgG Antibody Concentrations
Immunogenicity Set

<Antigen (units)>: Study *<study>*

Figure Specifications

By: Study, treatment and antigen, with separate plots for each study and antigen, presenting all treatment groups

x axis: Visit
x axis: Label: Visit
x axis: values: Day 1, Day 85

Y axis: Geo. Mean Concentration
Y axis Label: IgG Conc. (*<units>*)

Y axis values: As Appropriate

Study MVX0002 Legend:
Placebo - Blue, symbol = circle
25 µg GBS-NN/GBS-NN2 - Red, symbol = circle
50 µg GBS-NN/GBS-NN2 - Green, symbol = circle
GBS-NN/GBS-NN2 Overall - Purple, symbol = circle

Study MVX0003 Legend:
MVX0002 Placebo/Vaccine Naïve - Blue, symbol = square
MVX0002 25 µg GBS-NN/GBS-NN2 - Red, symbol = square
MVX0002 50 µg GBS-NN/GBS-NN2 - Green, symbol = square
MVX0002 GBS-NN/GBS-NN2 Overall - Purple, symbol = square
Overall - Black, symbol = square

Each treatment will use a different line type and will include '(N=X)' in the legend label

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
MVX0003 treatment groups defined in relation to the corresponding treatment received by each subject in the MVX0002 study.
Lower Limit of Quantification = xx.xx *<units>*. Results reported as <LLOQ were imputed as LLOQ/2.

Programming Note: For study MVX0002, treatments to be presented as Placebo, 25 µg GBS-NN/NN2, 50 µg GBS-NN/NN2 and GBS-NN/NN2 Overall. For study MVX0003, MVX0002 Placebo/Vaccine-Naïve, MVX0002 25 µg GBS-NN/NN2, MVX0002 50 µg GBS-NN/NN2, MVX0002 GBS-NN/NN2 Overall and Overall.
Programming Note: Figure will be replicated within an output for each study. A similar figure will be produced for Figure 14.5.1.2 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Table 14.5.1.3
Statistical Comparison of IgG Antibody Concentrations - Day 1 (MVX0003) vs Day 85 (MVX0002)
Immunogenicity Set

<Antigen (units)>

MVX0003 Day 1 Treatment	MVX0002 Day 85 Treatment	Number in Comparison	Geometric LSMeans (95% CI)		Geometric LSMean Ratio (90% CI)
			MVX0003 Day 1	MVX0002 Day 85	MVX0003 Day 1 / MVX0002 Day 85
50 µg GBS-NN/NN2	Placebo	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	25 µg GBS-NN/NN2	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	50 µg GBS-NN/NN2	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	GBS-NN/NN2 Overall	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Results obtained from a mixed effect ANOVA, with a fixed effect for study and random effect for subject. Vaccine-naïve subjects were not included in this analysis.

Programming Note: A similar table will be produced for Table 14.5.1.9 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Table 14.5.1.5
Statistical Comparison of Day 85 IgG Antibody Concentrations - MVX0003 vs MVX0002
Immunogenicity Set

<Antigen (units)>

MVX0003 Day 85 Treatment	MVX0002 Day 85 Treatment	Number in Comparison	Geometric LSMeans (95% CI)		Geometric LSMean Ratio (90% CI)
			MVX0003 Day 85	MVX0002 Day 85	MVX0003 Day 85 / MVX0002 Day 85
50 µg GBS-NN/NN2	Placebo	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	25 µg GBS-NN/NN2	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	50 µg GBS-NN/NN2	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
50 µg GBS-NN/NN2	GBS-NN/NN2 Overall	x	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Results obtained from a mixed effect ANOVA, with a fixed effect for study and random effect for subject. Vaccine-naïve subjects were not included in this analysis.

Programming Note: A similar table will be produced for Table 14.5.1.10 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Table 14.5.1.7
Statistical Comparison of MVX0003 Day 85 IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects
Immunogenicity Set

	Geometic LSMeans (95% CI)				Geometic LSMean Ratio (95% C.I.)		
Antigen	MVX0002 Placebo/ Vaccine-Naïve (N=X)	MVX0002 25 µg GBS-NN/NN2 (N=X)	MVX0002 50 µg GBS-NN/NN2 (N=X)	MVX0002 All GBS-NN/NN2 (N=X)	MVX0002 25 µg GBS-NN/NN2/ Placebo/Vaccine -Naïve	MVX0002 50 µg GBS-NN/NN2/ Placebo/Vaccine -Naïve	MVX0002 All GBS-NN/NN2/ Placebo/Vaccine -Naïve
GBS-NN	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)
GBS-NN2	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)	x.xx (x.xx-x.xx)

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
MVX0003 treatment groups defined in relation to the corresponding treatment received by each subject in the MVX0002 study.
Results obtained using an ANOVA with a fixed effect of treatment.

Programming Note: A similar table will be produced for Table 14.5.1.11 if there is a >5% difference in size of the IG and PP Sets.

Programming Note: For study MVX0002, treatments to be presented as Placebo, 25 µg GBS-NN/NN2, 50 µg GBS-NN/NN2 and GBS-NN/NN2 Overall. For study MVX0003, MVX0002 Placebo/Vaccine-Naïve, MVX0002 25 µg GBS-NN/NN2, MVX0002 50 µg GBS-NN/NN2, MVX0002 GBS-NN/NN2 Overall and Overall.

MVX0003
Table 14.5.1.9
Summary of Fold Increase in IgG Antibody Concentrations from Day 1 to Day 85
Immunogenicity Set

<Antigen (units)>

Study	Treatment Group	Study Day	IgG Antibody Concentration Day 85 / Day 1							
			n	Mean	SD	Geo. Mean (95% CI)	Min	Median	Max	IQR
MVX0002	Placebo (N=X)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	25 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	50 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	All GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
MVX0003	MVX0002 Placebo/Vaccine-Naïve (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	MVX0002 25 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	MVX0002 50 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	MVX0002 All GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
	Overall (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
MVX0003 treatment groups defined in relation to the corresponding treatment received by each subject in the MVX0002 study.

Programming Note: A similar table will be produced for Table 14.5.1.12 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Table 14.5.1.11
Summary of Fold Increase in IgG Antibody Concentrations from Day 85 MVX0002 to Day 85 MVX0003
Immunogenicity Set

<Antigen (units)>

Treatment Group	Study Day	IgG Antibody Concentration Day 85 MVX0003 / MVX0002							
		n	Mean	SD	Geo. Mean (95% CI)	Min	Median	Max	IQR
MVX0002 Placebo (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
MVX0002 25 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
MVX0002 50 µg GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x
MVX0002 All GBS-NN/NN2 (N=x)	DAY 85	x	x.xx	x.xxx	x.xx (x.xx, x.xx)	x.x	x.xx	x.x	x.x

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
MVX0003 treatment groups defined in relation to the corresponding treatment received by each subject in the MVX0002 study.
Vaccine-naïve subjects are not included in this summary.

Programming Note: A similar table will be produced for Table 14.5.1.13 if there is a >5% difference in size of the IG and PP Sets.

Programming Note: For study MVX0002, treatments to be presented as Placebo, 25 µg GBS-NN/NN2, 50 µg GBS-NN/NN2 and GBS-NN/NN2 Overall. For study MVX0003, MVX0002 Placebo/Vaccine-Naïve, MVX0002 25 µg GBS-NN/NN2, MVX0002 50 µg GBS-NN/NN2, MVX0002 GBS-NN/NN2 Overall and Overall.

MVX0003
Table 14.5.1.13
Summary of Day 85 Immune Response – Proportion above Threshold
Immunogenicity Set

<Antigen>

Study	Treatment Group	Number Non-missing	Antibody Concentration Threshold Number (%) of Subjects			
			>1 µg/mL	>2 µg/mL	>4 µg/mL	>8 µg/mL
MVX0002	Placebo (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	25 µg GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	50 µg GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	All GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MVX0003	MVX0002 Placebo/Vaccine-Naïve (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	MVX0002 25 µg GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	MVX0002 50 µg GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	MVX0002 All GBS-NN/NN2 (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Overall (N=x)	x	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Percentages calculated from the number of non-missing observations in the Immunogenicity Set within a treatment group.
Subjects will be included in all categories where their Day 85 antibody concentration increase is above the threshold.

Programming Note: Table will be produced for both GBS-NN and GBS-NN2 at Day 85. A similar table will be produced for Table 14.5.1.14 if there is a >5% difference in size of the IG and PP Sets.

MVX0003
Listing 16.2.1.1
Visit Dates
Safety Set

Subject	Visit	Date
xxx	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
xxx	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>
	<VISIT>	<DATE>

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming note: If not all visits start and end dates are equal then replace the Date column with two columns, one for Start Date and one for End Date.

MVX0003
Listing 16.2.1.2
Dose Administration
Safety Set

Subject	Visit	Pre-Dose Assessments Performed	Satisfy All Inclusion/ Exclusion Criteria	Eligible for Dosing	Date/Time of Dose	Dose Adminis-tered	Arm used for dosing	Expiry Date/Time	Batch Number
xxx	<VISIT>	<Y/N>	<Y/N>	<Y/N>	yyyy-mm-ddThh:mm	xxxxxxx	xxxx	yyyy-mm-ddThh:mm	xxxx
xxx	<VISIT>	<Y/N>	<Y/N>	<Y/N>	yyyy-mm-ddThh:mm	xxxxxx	xxxx	yyyy-mm-ddThh:mm	xxxx
xxx	<VISIT>	<Y/N>	<Y/N>	<Y/N>	yyyy-mm-ddThh:mm	xxxxxxx	xxxx	yyyy-mm-ddThh:mm	xxxx
xxx	<VISIT>	<Y/N>	<Y/N>	<Y/N>	yyyy-mm-ddThh:mm	xxxxxxx	xxxx	yyyy-mm-ddThh:mm	xxxx
xxx	<VISIT>	<Y/N>	<Y/N>	<Y/N>	yyyy-mm-ddThh:mm	xxxxxxx	xxxx	yyyy-mm-ddThh:mm	xxxx

Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.

MVX0003
Listing 16.2.1.3
Subject Disposition
All Consented Set

			Informed Consent/ Re-Consent		Screening Completion			End of Study		
Subject/ Screening Number	MVX0002 Subject Number	MVX0002 Treatment	Date/Time	Version	Screening Failure/ Non-Runner	Comment	Date Randomised*	Subject Status	Date of Completion/ Withdrawal	Reason for Withdrawal
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Placebo	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	N/A	N/A	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx	xxxxx	xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx	xxxxx	xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx	xxxxx	xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Active	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	N/A	N/A	xxxxxxxxx	xxxxx	xx		xxxxx	xxx	xxxxxxxxx	xxxxxxxx
xxx	xxx	Placebo	xxxxxxxxx	xxxxx	xx	xxxxx	xxxxx	xxx	xxxxxxxxx	xxxxxxxx

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* Randomised defined as the assignment of a subject number.

Programming Note: In column 1, the Subject Number should be presented for the subjects assigned a Subject Number, Screening Number for the screening failures/non-runners. Screening Failures/Non-Runners should be presented at the end of the listing.

MVX0003
Listing 16.2.1.4
Additional Comments
Safety Set

Subject	Form	Date	Visit	Comment Number	Comment
xxx	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxx	xxxxxxxxx	<VISIT>	x	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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MVX0003
Listing 16.2.2.1
Protocol Deviations
Safety Set

Subject	Deviation Number	Date of Deviation	Deviation Type	Details	Major/Minor
xxx	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
xxx	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
xxx	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx
	x	xxxxxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx

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MVX0003
Listing 16.2.3.1
Analysis Sets
All Consented Set

Subject/ Screening Number	Safety Set	Reason for Exclusion from Safety Set	Immunogenicity Set	Reason for Exclusion from Immunogenicity Set	Per Protocol Set	Reason for Exclusion from Per Protocol Set
xxx	Y		Y		Y	
xxx	Y		Y		N	xxxxxxxxxxxxxxxxxxxxxx
xxx	Y		Y		N	xxxxxxxxxxxxxxxxxxxxxx
xxx	Y		N	xxxxxxxxxxxxxxxxxxxxxx	N	xxxxxxxxxxxxxxxxxxxxxx
xxx	Y		Y		Y	
xxx	Y		N	xxxxxxxxxxxxxxxxxxxxxx	N	xxxxxxxxxxxxxxxxxxxxxx
xxx	Y		Y		Y	
xxx	Y		Y		Y	
xxx	Y		Y		Y	
xxx	Y		Y		Y	
xxx	Y		Y		Y	

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Programming Note: In column 1, the Subject Number should be presented for the subjects assigned a Subject Number, Screening Number for the screening failures/non-runners. Screening Failures/Non-Runners should be presented at the end of the listing.

MVX0003
Listing 16.2.4.1
Demographic Information
Safety Set

Subject Number	MVX0002 Study Partici-pation	MVX0002 Subject number	MVX0002 Treatment Group	Year of Birth	Age (yrs)	Screening Number	Ethnicity	Race	Height (m)	Weight (kg)	BMI (kg/m^2)
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Placebo	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	N	N/A	N/A	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	OTHER: xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Placebo	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	N	N/A	N/A	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxx	Y	xxx	Active	xxxx	xx	xxxx	xxxxxxx	xxx	xxx	xxx	xxx

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MVX0003
Listing 16.2.4.2
Medical History and Concurrent Conditions
Safety Set

Subject	Medical/ Surgical History Number	System Organ Class/ Preferred Term/ Reported Term	Date of Onset	Date Resolved/ Ongoing	Medication Taken/ Treatment Given	Clinically Significant
xxx	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	Y	N
	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxxxx	ONGOING	N	N
	x	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	N	Y

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MVX0003
Listing 16.2.4.3
Virology Test Results
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Source	Parameter	Result	Repeat Required
xxx	xxxxxx	xxxxxxT	Xxxxxx	*CRF*		xxxxxx	x
		xx:xx		*Lab Transfer*	xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
xxx	Xxxxxx	xxxxxxT	Xxxxxx	CRF	xxxxxx	xxxxxx	
		xx:xx		Lab Transfer	xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.4
COVID-19 RT-PCR Test Results
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Source	Parameter	Result	Repeat Required
xxx	xxxxxx	xxxxxxT	Xxxxxx	*CRF*		xxxxxx	x
		xx:xx		*Lab Transfer*	xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
xxx	Xxxxxx	xxxxxxT	Xxxxxx	CRF	xxxxxx	xxxxxx	
		xx:xx		Lab Transfer	xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	
					xxxxxx	xxxxxx	

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.5
Drugs of Abuse
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Source	Parameter	Result	Repeat Required
xxx	<VISIT>	xxxxxxTxx:xx	xxxxxx	*CRF*	xxxxxx	xxxxxx	x
				Lab Transfer	xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
	<VISIT>	xxxxxxTxx:xx	xxxxxx	*CRF*	xxxxxx	xxxxxx	x
				Lab Transfer	xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x
					xxxxxx	xxxxxx	x

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.6
Obstetric History
Safety Set

Subject	Parameter	Response	Date	Additional Information
Xxx	Child-bearing Potential	x		
	Contraception	xxxxxxxxxx		
	Post-Menopausal	x		xxxxxxxxxx
	Last Menstrual Period		xxxxxxx	xxxxxxxxxx
	Surgically Sterile	x	xxxxxxx	xxxxxxxxxx
	Hysterectomy	x	xxxxxxx	
	Additional Information			xxxxxxxxxx
Xxx	Child-bearing Potential	x		
	Contraception	xxxxxxxxxx		
	Post-Menopausal	x		xxxxxxxxxx
	Last Menstrual Period		xxxxxxx	xxxxxxxxxx
	Surgically Sterile	x	xxxxxxx	xxxxxxxxxx
	Hysterectomy	x	xxxxxxx	
	Additional Information			xxxxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.7
Pregnancy Test Results
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Source	Specimen Type	Parameter (units)	Result	Repeat Required
xxx	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*	SERUM		xxxxxx	xxx
				Lab Transfer	SERUM	xxxxxxxxxxx	xxxxxx	xxx
	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*	URINE		xxxxxx	xxx
				Lab Transfer	URINE	xxxxxxxxxxx	xxxxxx	xxx
	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*	URINE		xxxxxx	xxx
				Lab Transfer	URINE	xxxxxxxxxxx	xxxxxx	xxx

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.8
Post-Menopausal Assessment
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Source	Parameter (Units)	Result	Repeat Required
xxx	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*		xxxxxx	xxx
				Lab Transfer	xxxxxxxxxxx	xxxxxx	xxx
xxx	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*		xxxxxx	xxx
				Lab Transfer	xxxxxxxxxxx	xxxxxx	xxx
xxx	<VISIT>	xxxxxxxTxx:xx	xxxxxx	*CRF*		xxxxxx	xxx
				Lab Transfer	xxxxxxxxxxx	xxxxxx	xxx

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MVX0003
Listing 16.2.4.9
Substance Use History
Safety Set

	Alcohol	Smoking		
Subject	Average Units per week	Smoking Status	Date Stopped Smoking	Average number of cigarettes per day
xxx	x	xxxxxxx	yyyy-mm-dd	x
xxx	x	xxxxxxx	yyyy-mm-dd	x
xxx	x	xxxxxxx		
xxx	x	xxxxxxx		
xxx	x	xxxxxxx		
xxx	x	xxxxxxx		
xxx	x	xxxxxxx	yyyy-mm-dd	x

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.4.10
Inclusion/Exclusion Criteria Failures
Safety Set

Subject	Visit	Inclusion/ Exclusion	Criteria Code	Result
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx
xxx	<VISIT>	xxxxxx	xxxxxx	xxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

Programming Note: If there are no inclusion/exclusion criteria failures display 'All subjects complied with the inclusion/exclusion criteria'.

MVX0003
Listing 16.2.7.1
Non-Treatment Emergent Adverse Events - (1)
Safety Set

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Start Date/Time	Date Reported	End Date/Time/ Ongoing	Duration (dd:hh:mm)	Time from Dose (dd:hh:mm)	>=Day 85
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxxxxTxx:xx	xxxxx	xxxxxxTxx:xx	xx:xx:xx	xx:xx:xx	xxx

Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).

Programming note: The listing will be repeated for -
Listing 16.2.7.2 Treatment Emergent Adverse Events
Listing 16.2.7.3 Systemic Reactogenicity Adverse Events occurring within 72h of IMP
Listing 16.2.7.4 Local Reactogenicity Adverse Events occurring within 72h of IMP
Listing 16.2.7.5 Adverse Events after Day 85

MVX0003
Listing 16.2.7.1
Non-Treatment Emergent Adverse Events (2)
Safety Set

Subject	Event Number	System Organ Class/ Preferred Term/ Reported Term	Severity	Action	Causality	Outcome	SAE	Systemic Reacto-genicity	Local Reacto-genicity	Auto-Immune/ Clinically Relevant
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx
xxx	x	xxxxx/xxxxx/xxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxx	xxx	xxx

Produced: yyyy-mm-ddThh:mm - Page x of y
Duration: (Date/Time of Resolution-Date/Time of Onset) + 1 minute.
Time from Dose: (Date/Time of Onset-Date/Time of Start of Dose).
SAE = Serious Adverse Event.

Programming note: The listing will be repeated for -
Listing 16.2.7.2 Treatment Emergent Adverse Events
Listing 16.2.7.3 Systemic Reactogenicity Adverse Events occurring within 72h of IMP
Listing 16.2.7.4 Local Reactogenicity Adverse Events occurring within 72h of IMP
Listing 16.2.7.5 Adverse Events after Day 85

MVX0003
Listing 16.2.8.1
Biochemistry Data
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Parameter (Unit)	Result	Flag	Normal Range Low	Normal Range High	Alert Range Low	Alert Range High
xxx	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				Interpretation	xxxxx					
	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx	x.x	x.xx
				Interpretation	xxxxx					

Produced: yyyy-mm-ddThh:mm - Page x of y
H* = Above Alert Range; H = Above Normal Range; Lo = Below Normal Range; L* = Below Alert Range.

Programming note: A similar listing will be produced for Listing 16.2.8.2 and Listing 16.2.8.5.

MVX0003
Listing 16.2.8.3
Urinalysis Data
Safety Set

Subject	Visit	Sample Date/Time	Sample ID	Parameter (Unit)	Result	Flag	Normal Range Low	Normal Range High
xxx	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				Interpretation	xxxxx			
	<VISIT>	xxxxxxxxxx	xxxxx	xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				xxxxxxxxxx(xxx)	x.xx	x	x.x	x.xx
				Interpretation	xxxxx			

Produced: yyyy-mm-ddThh:mm - Page x of y
H = Above Normal Range; Lo = Below Normal Range.

Programming note: A similar listing will be produced for Listing 16.2.8.4.

MVX0003
Listing 16.2.9.1
Vital Signs Data
Safety Set

			Blood Pressure						
Subject	Visit/ Time Point	Date/Time	Systolic (UNITS)	Diastolic (UNITS)	Pulse (UNITS)	Tympanic Temperature (UNITS)	Respiration Rate (UNITS)	Review	Comments
xxx	<VISIT>	xxxxxxTxx:xx	xxx	xxx	xx	xxx	xx	xxxxx	
	<VISIT>	xxxxxxTxx:xx	xxx	xxx	xx	xxx	xx	xxxxx	
	<VISIT>	xxxxxxTxx:xx	xxx	xxx H	xx	xxx	xx	xxxxx	xxxxxxxxx
	<VISIT>	xxxxxxTxx:xx	xxx	xxx	xx	xxx	xx	xxxxx	
	<VISIT>	xxxxxxTxx:xx	xxx	xxx	xx	xxx	xx	xxxxx	
	<VISIT>	xxxxxxTxx:xx	xxx	xxx	xx	xxx L	xx	xxxxx	xxxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y
H = Above Normal Range; L = Below Normal Range.

MVX0003
Listing 16.2.10.1
Physical Examination Data
Safety Set

Subject	Visit	Date/Time	Evaluation	Reason if Date Differs from Scheduled Visit
xxx	<VISIT>	xxxxxxxxxxxxxx	xxxxxxxx	
xxx	<VISIT>	xxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxx
xxx	<VISIT>	xxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.11.1
12-Lead ECG Data
Safety Set

Subject	Visit	Date/Time	Heart Rate (UNITS)	PR Interval (UNITS)	QRS Width (UNITS)	QT Interval (UNITS)	QTcF Interval (UNITS)	Interpretation	Comments
xxx	<VISIT>	xxxxxxxTxx:xx	xxx L	xxx	xxx	xxx	xxx	xxxx	xxxxxxxxxx
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx H	xxxx	xxxxxxxxxxx
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx H	xxxx	xxxxxxxxxxx
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	
xxx	<VISIT>	xxxxxxxTxx:xx	xxx	xxx	xxx	xxx	xxx	xxxx	

Produced: yyyy-mm-ddThh:mm - Page x of y
H = Above Normal Range; L = Below Normal Range.

MVX0003
Listing 16.2.12.1
Prior and Concomitant Medications
Safety Set

<*Treatment Phase*> (i.e. *Prior, Prior and Ongoing, Concomitant*)

Subject	Medication Number	Medication	Dose	Dose Unit	Frequency	Route	Start Date/Time	Stop Date/Time/ Ongoing	Indication
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxxxx	xx	xxxxxxxx	xxxx	xxxxxxxTxx:xx	xxxxxxxTxx:xx	xxxxxxxxx
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxxxx	xx	xxxxxxxx	xxxx	xxxxxxxTxx:xx	xxxxxxxTxx:xx	xxxxxxxxx
xxx	x	xxxxxxxx/ xxxxxxxx/ xxxxxxxx	xxxxx	xx	xxxxxxxx	xxxx	xxxxxxxTxx:xx	xxxxxxxTxx:xx	xxxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y
A medication will be regarded as prior if it starts prior to administration of study drug administration.

MVX0003
Listing 16.2.13.1
Injection Site Reaction Assessments
Safety Set

Subject	Visit	Time Point	Date/Time of Assessment	Type of Reaction	Reaction Experienced	Diameter (cm)	Photos Taken
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	Redness	x	xx	x
				Bruising	x		
				Induration	x	xx	x
				Itching	x	xx	x
				Pain	x	xx	x
		<TIME POINT>	xxxxxxTxx:xx	Redness	x	xx	x
				Bruising	x		
				Induration	x		
				Itching	x		
				Pain	x	xx	x

Produced: yyyy-mm-ddThh:mm - Page x of y
Injection site reactions are also captured as adverse events. Injection site reactions recorded by the subjects within the diary cards from Day 1 to Day 7 are recorded as adverse events.

MVX0003
Listing 16.2.14.1
IgG Antibody Concentrations and Fold Increase Data
Safety Set

<Antigen>

Subject	MVX0002 Treatment Group	Visit	Study	Sample Date/ Time	Sample ID	Conc. (µg/mL)	Change from Baseline	Fold Increase D85/D1	Fold Increase MVX0003 D85/ MVX0002 D85
xxx	*<Treatment>*	Day 1	MVX0002	xxxxxxTxx:xx	N/A	xxx			
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx			
		Day 85	MVX0002	xxxxxxTxx:xx	N/A	xxx	xxx	x.xx	
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx	xxx	x.xx	x.xx
xxx	*<Treatment>*	Day 1	MVX0002	xxxxxxTxx:xx	N/A	xxx			
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx			
		Day 85	MVX0002	xxxxxxTxx:xx	N/A	xxx	xxx	x.xx	
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx	xxx	x.xx	x.xx
xxx	N/A	Day 1	MVX0002	N/A	N/A	N/A			
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx			
		Day 85	MVX0002	N/A	N/A	N/A	N/A	N/A	
			MVX0003	xxxxxxTxx:xx	xxxxxxx	xxx	xxx	x.xx	N/A

Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Baseline defined as Day 1.
Lower Limit of Quantification = xx.xx *<units>*. Results reported as <LLOQ were imputed as LLOQ/2 for the derivation of change from baseline and fold increase.

MVX0003
Figure 16.2.14.1
Individual IgG Antibody Concentrations
Safety Set

Subject <*xxx*> - MVX0002 Treatment <*xxxxx*>

Figure Specifications

Procedure: SGPANEL

By: Study and antigen, one plot per subject presenting both studies and antigens

X Axis: Visit
X Axis Label: Visit
X Axis Values: Day 1, Day 85

Y Axis: Antibody Concentration
Y Axis Label: Antibody Concentration (units)
Y Axis Values: As per data

Legend: MVX0002 GBS-NN - symbol = circle, colour = blue, line = dashed
MVX0002 GBS-NN2 - symbol = circle, colour = red, line = dashed
MVX0003 GBS-NN- symbol = square, colour = blue, line = solid
MVX0003 GBS-NN2- symbol = square, colour = red, line = solid

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
MVX0003 Treatment: A single 0.5 mL injection of 50 µg GBS-NN/NN2 on Day 1.
Lower Limit of Quantification = xx.xx <*units*>. Results reported as <LLOQ were imputed as LLOQ/2.

MVX0003
Listing 16.2.14.2
Raw Statistical Analysis of IgG Antibody Concentrations - Day 1(MVX0003) vs Day 85 (MVX0002)
Immunogenicity Set

Will be populated with raw ANOVA output.

Source Listing: 16.2.14.1; Produced: yyyy-mm-ddThh:mm - Page x of y
Results obtained from a mixed effect analysis of variance (ANOVA) model, with fixed effect for study and random effect for subject.

Programming Note: Similar listings will be produced for –
*Listing 16.2.14.*3 Raw Statistical Analysis of IgG Antibody Concentrations for Day 85 – MVX0003 vs MVX0002 (IG Set)
Listing 16.2.14.4 Raw Statistical Analysis of IgG Antibody Concentrations of Booster Subjects vs Placebo/Vaccine-Naïve Subjects (IG Set)
Programming Note: If there is a >5% difference in size of the IG and PP Sets, the listings will be repeated using the PP Set (Listing 16.2.14.5, 16.2.14.6, 16.2.14.7).

MVX0003
Listing 16.2.15.1
Diary Card Completion
Safety Set

Subject	Visit	Diary Card Issued	Diary Card Returned	If No, specify
xxx	<VISIT>	<Y/N>	<Y/N>	xxxxxx
	<VISIT>	<Y/N>	<Y/N>	
	<VISIT>	<Y/N>	<Y/N>	
	<VISIT>	<Y/N>	<Y/N>	
xxx	<VISIT>	<Y/N>	<Y/N>	xxxxxx
	<VISIT>	<Y/N>	<Y/N>	
	<VISIT>	<Y/N>	<Y/N>	
	<VISIT>	<Y/N>	<Y/N>	

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.15.2
PD Sampling Information for Antibody Response
Safety Set

Subject	Visit	Time Point	Sample Date/ Time	Sample ID	Repeat Taken	Comments
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxx
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxx
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.15.3
Exploratory [redacted] Sampling Information
Safety Set

Subject	Visit	Time Point	Sample Date/ Time	Sample ID	Repeat Taken	Comment
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxxx
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	

Produced: yyyy-mm-ddThh:mm - Page x of y

MVX0003
Listing 16.2.15.4
Blood Sample for Future Work Information
Safety Set

Subject	Visit	Time Point	Sample Date/ Time	Sample ID	Repeat Taken	Comment
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxxx
xxx	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxxx
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	
	<VISIT>	<TIME POINT>	xxxxxxTxx:xx	xxxxxxx	x	xxxxxxxxx

Produced: yyyy-mm-ddThh:mm - Page x of y

16 APPENDICES

16.1 NORMAL RANGES

Vital Signs Normal Ranges:

Parameter	Normal Range	Units
Pulse Rate	40-100	Beats per Minute (bpm)
Systolic Blood Pressure	90-140	mmHg
Diastolic Blood Pressure	50-90	mmHg
Respiratory Rate	12-18	Breaths per Minute
Oral Temperature	>=35.0 to <=37.5	Degrees Celsius (°C)

12-Lead ECG Normal Ranges:

Parameter	Normal Range	Units
Heart Rate	40-100	Beats per Minute (bpm)
PR Interval	120-220	mSec
QRS Width	70-120	mSec
QT Interval	N/A	mSec
QTcB Interval	350 – 450	mSec

DocuSign

Certificate Of Completion

Envelope Id: 7C577A38177D4CDD9D0A96731B6EA7C0
Status: Completed
Subject: Please DocuSign: Minervax MVX0003 - RD751 34984 SAP Final 1.0 09SEP2022.docx
Source Envelope:
Document Pages: 91
Signatures: 4
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Envelope Originator:
[redacted]
Unit 29 Simbec Research Ltd
Merthyr Tydfil Industrial Park, Pentrebach
Merthyr Tydfil , Merthyr Tydfil CF464DR
[redacted]

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Status: Original
09-Sep-2022 | 11:09
Holder: [redacted]
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Signer Events	Signature	Timestamp
[redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: E52D5091-E1F3-4A3C-8834-63AB44FB4D67 Using IP Address: 86.182.15.192 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 09-Sep-2022 | 11:13 Viewed: 09-Sep-2022 | 12:27 Signed: 09-Sep-2022 | 12:28
Electronic Record and Signature Disclosure: Accepted: 19-Oct-2020 | 13:24 ID: e4b95c21-c476-4ebb-b0b5-fb03ad0eaedd		
[redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: 96FA693E-AE7F-47B3-9C06-240874D69B85 Using IP Address: 94.147.76.14 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 09-Sep-2022 | 11:13 Viewed: 09-Sep-2022 | 12:35 Signed: 09-Sep-2022 | 12:35
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Signer Events	Signature	Timestamp
[redacted] [redacted] Simbec Orion Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: F3E94C12-2FE9-4BD1-802D-A6C1E65CE70F Using IP Address: 51.219.87.100 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I am the author of this document	Sent: 09-Sep-2022 | 11:13 Viewed: 09-Sep-2022 | 11:15 Signed: 09-Sep-2022 | 11:15
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
[redacted] [redacted] Senior Project Director Simbec Orion Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: B4FBBAAC-77C3-402E-B63B-5F1F6A964DB3 Using IP Address: 51.219.87.100 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 09-Sep-2022 | 11:13 Viewed: 09-Sep-2022 | 11:28 Signed: 09-Sep-2022 | 11:28
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In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	09-Sep-2022 | 11:13
Certified Delivered	Security Checked	09-Sep-2022 | 11:28
Signing Complete	Security Checked	09-Sep-2022 | 11:28
Completed	Security Checked	09-Sep-2022 | 12:35

Payment Events	Status	Timestamps

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ii. send us an email to jim.kendall@simbecorion.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

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- Until or unless you notify Orion Clinical Services Limited (acting for itself and on behalf of its Affiliates) - Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Orion Clinical Services Limited (acting for itself and on behalf of its Affiliates) - Part 11 during the course of your relationship with Orion Clinical Services Limited (acting for itself and on behalf of its Affiliates) - Part 11.