Protocol Number: VXA-NVV-108

Official Title: A Phase I, Multicenter, Randomized, Double-blind, Placebo-controlled Single Dose, Dose-ranging Study to Evaluate the Safety, Tolerability, and Immunogenicity of Orally Administered Bivalent GI.1/GII.4 Norovirus Vaccine in Healthy Lactating Females ≥ 18 Years Old and Their Breast-feeding Infants

NCT Number: NCT07254728

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STATISTICAL ANALYSIS PLAN

A phase I, multicenter, randomized, double-blind, placebo-controlled single dose, dose-ranging study to evaluate the safety, tolerability, and immunogenicity of orally administered bivalent GI.1/GII.4 norovirus vaccine in healthy lactating females ≥ 18 years old and their breast-feeding infants

PROTOCOL NO.: VXA-NVV-108

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SAP APPROVAL

By my signature, I confirm that this SAP has been reviewed by Vaxart, Inc. and has been approved for use on the VXA-NVV-108 study:

Name	Title / Company	Signature	Date
[redacted]			

Table of contents

1. INTRODUCTION 8
2. Project OverView 9
2.1 Study Design 9
2.2 Objectives 12
2.3 Endpoints 12
2.4 Sample Size 14
2.5 Randomization 14
3. STATISTICAL CONSIDERATIONS 16
3.1 General Considerations 16
3.2 Key Definitions 17
3.3 Inferential Analyses 17
3.4 Multiple Comparisons and Multiplicity Adjustments. 18
3.5 Handling of Missing Data 18
3.6 Coding of Events and Medications 19
3.7 Treatment arms 19
4. ANALYSIS POPULATIONS 20
4.1 Population Descriptions 20
5. Subject DISPOSITION AND ANALYSIS POPULATIONS 21
6. PROTOCOL DEVIATIONS 22
7. DEMOGRAPHIC AND BASELINE INFORMATION 23
7.1 Demographics 23
7.2 Medical /Surgical history 23
7.3 Serology 23
7.4 Urine Drug Screen 23
7.5 Alcohol Test 23
8. TREATMENT EXPOSURE 24
9. PRIOR AND CONCOMITANT MEDICATIONS 25
10. PHARMACOKINETICS 26
11. PHARMACODYNAMICS 27
12. EFFICACY 28
13. SAFETY 29
13.1 Solicited Symptoms of Reactogenicity 29
13.2 Unsolicited AE from Day 1 to Day 29 Post-Vaccination 29
13.3 Serious Adverse Events 30
13.4 New Onset of Chronic Illness 31
13.5 Adverse Event of Special Interest 31

13.6 Vital Signs *32*
13.7 Physical Examinations *32*
13.8 Pregnancy Test Results *32*
14. IMMUNOGENICITY 33
15. CHANGES TO THE PLANNED ANALYSIS 37
16. INTERIM AND FINAL ANALYSIS 38
17. SOFTWARE 39
18. TABLES 40
19. LISTINGS 44
20. FIGURES 46
21. REFERENCES 47

List of Abbreviations

Abbreviation	Description
AE	Adverse event
AESI	Adverse event of special interest
AEFI	Adverse events following immunization
ASC	Antibody secreting cells
ATC	Anatomical Therapeutic Class
AU	Arbitrary Unit
BMI	Body mass index
BT50	Blocking Titer 50
CI	Confidence Intervals
eCRF	Electronic case report form
CS	Clinically Significant
CSR	Clinical Study Report
DBP	Diastolic blood pressure
EDC	Electronic Data Capture
EOS	End of Study
ET	Early Termination
GCP	Good Clinical Practice
GI.1	Norovirus genogroup I.1
GII.4	Norovirus genogroup II.4
GRAS	Generally recognized as safe
HBsAg	Hepatitis B surface antigen
HBGA	Histo-blood group antigen
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
ICF	Informed Consent Form
IP	Investigational Product
ITT	Intent to treat
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IQR	Interquartile Range
IU	Infectious Units
LLD	Lower Limit of Detection
LLOQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
MSD	Meso Scale Discovery
N/A	Not Applicable
NCS	Not Clinically Significant
NK	Not Known
NOCI	New Onset of Chronic Illness
NoV	Norovirus
PD	Pharmacodynamic
PI	Principal investigator
PK	Pharmacokinetic
PT	Preferred Term
SAE	Serious adverse event
SAP	Statistical analysis plan
SBP	Systolic blood pressure
SD	Standard Deviation
SMC	Safety Monitoring Committee

Abbreviation	Description
S.I.	International System of Units
SoA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment-emergent adverse event
VP1	Viral Protein 1, major capsid protein of norovirus
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary

1. INTRODUCTION

The following Statistical Analysis Plan (SAP) provides the outline for the statistical analysis of the data collected from the VXA-NVV-108 study (protocol version *2.0* dated *25 July 2023*) and its associated electronic case report forms (eCRF) Version 3.0, dated *06 December 2023*.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post hoc, or unplanned, exploratory analyses performed will be clearly identified as such in the final CSR.

The preparation of this SAP has been based on the International Council for Harmonization (ICH) E9 and Good Clinical Practice (GCP) E6 guidelines.

2. PROJECT OVERVIEW

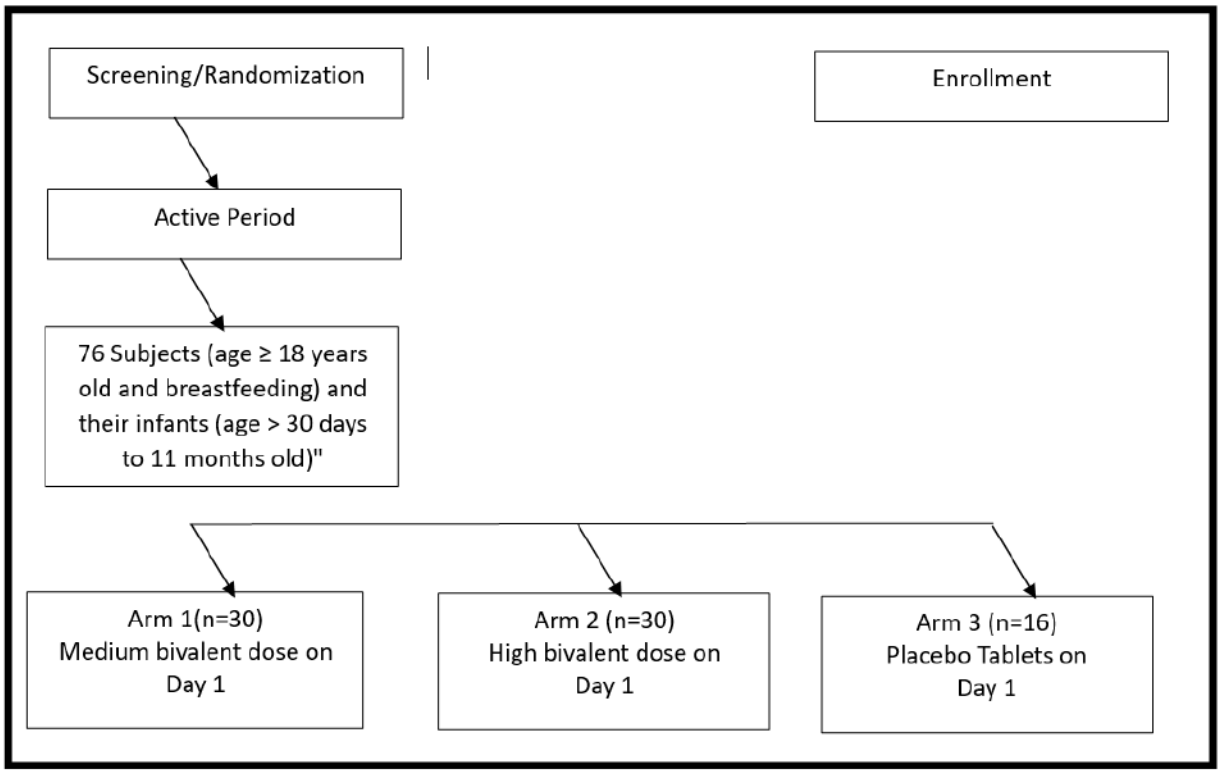
2.1 Study Design

This is a multi-center, double-blind, randomized, placebo-controlled, single dose, dose ranging study in healthy, breastfeeding, female volunteers (≥18 years). The study will randomize 76 subjects and their breastfed infants aged >30 days to 11 months of age into three arms.

After reviewing and signing an informed consent, the subjects will undergo screening assessments to determine study eligibility up to a 45-day Screening Period.

On Day 1 of the randomized portion, subjects will be randomized in a 30:30:16 ratio to one of the three treatment arms to receive active vaccine at medium dose or high dose or placebo, as follows (Figure 1):

Figure 1: Study Design



After vaccination on Day 1, the study will include an Active Study Period that runs through 4 weeks after administration (Day 29), and a Follow-up Period of one-year post-dose for safety and duration of immune response. Study assessments will be conducted as shown in the SoA (Table 1). In addition, subjects will be contacted by phone between site visits to monitor for safety as specified in the SoA (Table 1).
A subject is considered to have completed the study if she completes the study active period at Day 29 (End of Study Active Period). Following completion of the Day 29 visit by all subjects the database will be cleaned and locked and the study unblinded, except the medical monitoring and pharmacovigilance team including anyone at the Sponsor, CRO and sites(s). The Topline Clinical Study Report (CSR) will be written based on the Day 29 clean datasets.

A subject is considered to have completed the Follow-up Period if she remains in the study through Day 365 (Month 12). Following completion of the Day 365 tele-health appointment for all subjects, the safety database will be cleaned and locked, and data collected during the Follow-up Period will be included in a CSR addendum.

All subjects will be monitored for Solicited Symptoms of Reactogenicity (GI and systemic) for 1 week following the study drug dose (until Day 8 (+2 days) scheduled site visit) and unsolicited AEs for 28 days post study drug dose (until Day 29 scheduled site visit) during the active period. Subjects will then enter the Follow-up period after Day 29 and will be monitored for specified unsolicited adverse events (SAEs, AESIs, and NOCIs) through Day 365 (Month 12) for safety and durability of immune response. Subjects will provide samples (nasal, saliva, serum, breast milk, and infant stool for evaluation of immunogenicity as specified in the Schedule of Activities (SoA) (Table 1).

Table 1: Schedule of Activities

	Screening	Active Study Period				Follow-up Period					
Study Day	**Day -45 to Day -1**	**Day 1**	**Day 8 (ET)[f]**	**Day 15**	**Day 29 (ET)[f]**	**Month 2 Day 60[*]**	**Month 4 Day 120**	**Month 6 Day 180**	**Month 8 Day 240**	**Month 10 Day 300**	**Month 12 Day 365**
Telephone call visit				✆			✆		✆	✆	✆
Visit Window (days)			+2	±2	±2	±7	±7	±7	±7	±7	±7
Informed consent	X										
Inclusion/Exclusion	X	X									
Demographics	X										
Medical history[*]	X	X									
Serology[a]	X										
Urine drug screen	X										
Alcohol test	X	X									
Pregnancy Test[b]	X	X									
Physical examination	X	X[c]	X[c]		X[c]						
Vital Signs[d]	X	X	X		X						
Study Drug Administration		X									
Distribute Solicited Symptom Diary		X									
Review Solicited Symptom Diary[e]			X[f]								
Review prior & concomitant medication	X	X	X	X	X						
Query for AEs, SAEs, AESIs and NOCIs		X	X	X	X	X[g]	X[g]	X[g]	X[g]	X[g]	X[g]

	Screening	Active Study Period				Follow-up Period					
Study Day	**Day -45 to Day -1**	**Day 1**	**Day 8 (ET)[f]**	**Day 15**	**Day 29 (ET)[f]**	**Month 2 Day 60***	**Month 4 Day 120**	**Month 6 Day 180**	**Month 8 Day 240**	**Month 10 Day 300**	**Month 12 Day 365**
Telephone call visit				✆			✆		✆	✆	✆
Visit Window (days)			+2	±2	±2	±7	±7	±7	±7	±7	±7
Sample Collection for Immunogenicity Assessments											
Serum sample - BT50, VP1 specific IgA and IgG		X	X		X			X			
Nasal Swab (SAM™ Device) - VP1 specific IgA		X	X		X	X		X			
Saliva Sample - VP1 specific IgA		X	X		X	X		X			
Breastmilk - VP1 specific IgA, Enterocyte culture neutralizing antibodies, and BT50[h]		X	X		X	X		X			
Infant Stool - VP1 specific IgA		X			X	X					

Notes:
Tele-health appointment (by phone)
a F- human immunodeficiency virus (HIV), Hepatitis B surface antigen (HBsAg) or Hepatitis C virus (HCV)
b Serum pregnancy tests will be done at screening. Point-of-Care urine pregnancy test will be performed before dosing on Day 1 and women found positive with urine pregnancy test will not be enrolled during this study.
c Targeted exam: at a minimum, assessments of the skin, respiratory system, cardiovascular system, and GI (abdomen, liver, and spleen) will be included.
d Blood pressure, heart rate, and respiratory rate will be measured after the subject has been resting in a sitting position for 5 minutes.
e At the discretion of PI and/or per subject request to evaluate any of the expected reactogenicity symptoms or any unexpected symptoms of concern, a contact must occur as soon as possible between the subject and the Investigator, or a medically qualified member of the study site staff, to assess if an unscheduled visit is required.
f Early termination assessments. Review of solicited symptoms should be included if the subject drops out before Day 8. Day 29 procedures should be performed if the subject drops out before Day 29 on the day of early termination.
g TEAEs will only be collected during the Active Study period (from time of first dose through 4 weeks post dose). Only SAEs, AESIs and NOCIs will be collected during the Follow-up Period.
h Breastmilk VP1 specific IgA will be tested at the indicated intervals in the table. Breastmilk enterocyte culture neutralizing antibodies and BT50 will be tested at various time points if feasible.
* Also collect the infant's medical record at screening and day 1 and the infant's updated vaccine record at D60 or later

2.2 Objectives

2.2.1 Primary objective(s)

- **Safety**
  - To determine the safety and tolerability of oral bivalent dosing regimen of GI.1 and GII.4 norovirus vaccine administration in healthy lactating female participants.

- **Immunogenicity**
  - To determine the short-term immunogenicity of oral bivalent GI.1/GII.4 norovirus vaccine administration in healthy lactating female participants and most critically, the association with vaccine specific antibody responses in breast milk.

2.2.2 Secondary objective(s)

- **Safety**
  - To determine the long-term safety of bivalent GI.1/GII.4 norovirus vaccine through 12 months after the last vaccination.
- **Immunogenicity**
  - To assess the long-term immunogenicity of oral bivalent GI.1/GII.4 norovirus vaccine administration in healthy lactating female participants and most critically, the association with vaccine specific antibody responses in breast milk.

2.2.3 Exploratory objective(s)

- **Immunogenicity**
  - To determine the additional immunogenicity parameters of bivalent GI.1/GII.4 norovirus vaccine including immunogenicity response in breastfed infants.
  - To determine the clinical effects in subjects presenting with acute gastroenteritis symptoms during the study period.

2.3 Endpoints

2.3.1 Primary endpoints

- **Safety:**
  - Frequency, duration, and severity of solicited symptoms of reactogenicity (local, systemic) for 1 week following each dose of study drug.
  - Frequency, duration, and severity of unsolicited treatment-emergent adverse events (TEAEs), serious AEs (SAEs), adverse events of special interest (AESIs), and new onset of chronic illness (NOCIs) through the active period (4 weeks post last dose).

- **Immunogenicity:**
  - Serum VP1 specific (GI.1 and GII.4) IgA through the active period measured by Meso Scale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8 and Day 29
    - Geometric mean fold rise (GMFR) from Day 1 to Day 8 and from Day 1 to Day 29
    - The number of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint.
  - Breast Milk VPI specific (GI.1 and GII.4) IgA through the active period measured by Meso Scale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8, and Day 29
    - Geometric mean fold rise (GMFR) from Day 1 to Day 8, and from Day 1 to Day 29

- The number of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in breast milk VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint.

2.3.2 Secondary endpoints

- **Safety**
  - Frequency, duration, and severity of all SAEs, AESIs, and NOCIs through 12 months after last study drug dose
- **Immunogenicity**
  - Serum VP1 specific (GI.1 and GII.4) IgA through 6 months after study drug dose measured by Meso Scale Discovery (MSD) by dose level
    - Geometric mean concentration (GMC) at Day 180
    - Geometric mean fold rise (GMFR) from Day 1 to Day 180
    - The number of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgA (GI.1 and GII.4) between Day 1 and Day 180.
  - Breast Milk VP1 specific (GI.1 and GII.4) IgA through 6 months after study drug dose measured by Meso Scale Discovery (MSD) by dose level
    - Geometric mean concentration (GMC) at Day 60 and Day 180
    - Geometric mean fold rise (GMFR) from Day 1 to Day 60 and from Day 1 to Day 180
  - Serum VP1 specific (GI.1 and GII.4) IgG through 6 months after study drug dose measured by Meso Scale Discovery (MSD) by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8, Day 29, and Day 180
    - Geometric mean fold rise (GMFR) from Day 1 to Day 8, from Day 1 to Day 29, and from Day 1 to Day 180
    - The number of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgG (GI.1 and GII.4) between Day 1 and any other timepoint.
  - Serum Blocking titers 50 (BT50) (GI.1 and GII.4) through 6 months after study drug dose measured by Histo-blood group antigen (HBGA) assay by dose level
    - Geometric mean titer (GMT) at Day 1and Day 29
    - Geometric mean fold rise (GMFR) from Day 1 to Day 29,
    - The number of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMT rise or greater in serum blocking titers 50 (BT50) (GI.1 and GII.4) between Day 1 and any other timepoint.

2.3.3 Exploratory endpoints

- **Efficacy:**
  - Occurrence of norovirus acute gastroenteritis

- **Immunogenicity:**
  - Saliva VP1 specific (GI.1 and GII.4) IgA from lactating mother measured by MSD by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8, Day 29, Day 60 and Day 180

- Geometric mean fold rise (GMFR) from Day 1 to Day 8, from Day 1 to Day 29, from Day 1 to Day 60, and from Day 1 to Day 180

- Nasal VP1 specific (GI.1 and GII.4) IgA from lactating mother measured by Meso Scale Discovery (MSD) by dose level
  - Geometric mean concentration (GMC) at Day 1, Day 8, Day 29, Day 60 and Day 180
  - Geometric mean fold rise (GMFR) from Day 1 to Day 8, from Day 1 to Day 29, from Day 1 to Day 60, and from Day 1 to Day 180
- Infant stool VP1 specific (GI.1 and GII.4) IgA measured by Meso Scale Discovery (MSD) by dose level
  - Geometric mean concentration (GMC) Day 1, Day 29, and Day 60
  - Geometric mean fold rise (GMFR) from Day 1 to Day 29 and from Day 1 to Day 60
- Breast Milk Antibody blocking titers 50 (BT50) (GI.1 and GII.4) measured by BT50 assay by dose level
  - Individual subject titers on samples and some timepoints that have a high likelihood of success, assuming the assay works in breast milk samples
- Breast Milk neutralizing antibody titers (GI.1 and GII.4) measured by norovirus human intestinal enteroid model.
  - Individual subject titers on samples and sometime points that have a high likelihood of success, under the assumption that the assay works in breast milk samples. At the date of this protocol, only serum GII.4 neutralizing antibodies have been successfully measured.

2.4 Sample Size

A sample size of 76 randomized subjects (30 each in medium and high dose levels and 16 in placebo) is not based on formal statistical testing but rather based on clinical judgement and predicted to yield meaningful safety and immunogenicity results. Placebo was added for safety comparison.

2.5 Randomization

Assignment of a Subject Number:

New subjects once deemed eligible and enrolled in the study will also receive a randomization number and treatment assignment, based on the blinded randomization schedule. The subject number will be used as the primary identifier for the complete duration of the study. After the subject signs the informed consent form (ICF), the Investigator (or designee) will enter the subject into the Screening Log, once randomized or screen failed their data will be entered into the eCRF.

Randomization:

After signing an informed consent, the subjects will undergo screening assessments to determine study eligibility over a 45-day Screening Period. All subjects who sign a study specific informed consent form will have data entered into the EDC. On Day 1, subjects will be randomized in a 30:30:16 ratio to one of the three treatment arms to receive active vaccine or placebo as follows (Table 2).

Table 2: Study Arms

Arm Title*	Arm 1	Arm 2	Arm 3
Arm Description	Medium Dose Bivalent GII.4/GI.1 vaccine	High Dose Bivalent GII.4/GI.1 vaccine	Placebo
Per Strain Dose (IU) +/-0.5 log	5×10^{10}	1×10^{11}	N/A
Total Dose (IU/dose)	1×10^{11}	2×10^{11}	N/A

3. STATISTICAL CONSIDERATIONS

Data will be handled and processed per the sponsor's representative ([redacted] Standard Operating Procedures (SOPs) and guidelines, which are written based on the principles of good clinical practice (GCP) E6.

3.1 General Considerations

All data collected on the electronic case report form (eCRF) will be presented in the data listings and will be sorted by treatment arm, subject number and visit, where applicable. All descriptive summaries will be presented by treatment arm and nominal visit.

All safety and immunogenicity descriptive summaries will be presented by treatment arm and nominal visit.

Unless otherwise stated, the following methods will be applied:

- Continuous variables: Descriptive statistics will include the number of non-missing values (n), arithmetic mean, standard deviation (SD), median, minimum and maximum values.

  The minimum and maximum values will be displayed to the same decimal precision as the source data, the arithmetic mean, SD and median values will be displayed to one more decimal than the source data for the specific variable.

  95% Confidence Intervals (CIs), mean differences (among treatments and from baseline) and least-square (LS-Means) values will be displayed to one more decimal than the source data for a specific variable. P-values will be displayed to 3 decimal places.

  The appropriate precision for derived variables will be determined based on the precision of the data on which the derivations are based, and statistics will be presented in accordance with the above-mentioned rules.

- Categorical variables: Descriptive statistics will include counts and percentages per category. The denominator in all percentage calculations will be the number of subjects in the relevant analysis population with non-missing data, unless specifically stated otherwise. Percentages will be displayed to one decimal place. Proportions will be displayed to 3 decimal places.

  95% Confidence Intervals (CIs), difference in proportions and other categorical parameters will be displayed to one decimal place for percentages. Proportions will be displayed to 3 decimal places. p-values will be displayed to 3 decimal places.

- Repeat/unscheduled assessments: Only values collected at scheduled study days/time points will be presented in summary tables. If a repeat assessment was performed, the result from the original assessment will be presented as the result at the specific visit/time point. All collected data will be included in the data listings.
- Assessment windows: All assessments will be included in the data listings and no visit windows will be applied to exclude assessments that were performed outside of the protocol specified procedure windows.
- Result display convention: Results will be center aligned in all summary tables and listings. Subject identifiers visit and parameter labels may be left-aligned if required.
- Date and time display conventions: The following display conventions will be applied in all outputs where dates and/or times are displayed:

  Date only: YYYY-MM-DD

  Date and time: YYYY-MM-DD HH:MM

If only partial information is available, unknown components of the date or time will be presented as 'NK' (not known), i.e., '2016-NK-NK'. Times will be reported in military time.

3.2 Key Definitions

The following definitions will be used:

- Baseline: The baseline value is defined as the last available valid (quantifiable continuous or categorical value), non-missing observation for each subject prior to vaccine administration. The mean will be chosen for continuous variables. Repeat and unscheduled assessments will be included in the derivation of the baseline values.
- Change from Baseline: The change from baseline value is defined as the difference between the result collected/derived at a post-baseline visit/time point and the baseline value and will be calculated for all continuous parameters using the following formula:

  Change from Baseline Value = Result at Visit/Time Point – Baseline Value

  The change from baseline value will only be calculated if the specific post-baseline visit/time point result and the baseline value for the parameter are both available and will be treated as missing otherwise.
- Fold Change from Baseline: The fold change from baseline value is defined as the post baseline value divided by baseline value in original scale and point will be calculated for all continuous parameters using the following formula:

  Fold Change from Baseline Value = Post Baseline Result (in original scale) / Baseline Value (in original scale) if the baseline value is not equal to zero or missing.
- Study day: The study day of an event is defined as the relative day of the event starting with the date of the first study drug administration (reference date) as Day 1 (there will be no Day 0).

  The study day of events occurring before the first study drug administration will be calculated as:

  Study Day = (Date of Event - Date of First Study Drug Administration)

  For events occurring on or after Day 1, study day will be calculated as:

  Study Day = (Date of Event - Date of First Study Drug Administration) + 1

  Study days will only be calculated for events with complete dates and will be undefined for events that are 'Ongoing' at the end of the study.

  Relative days compared to an alternative reference point will be calculated similarly, but the alternative starting reference start date will be used instead of the date of the first study drug dosing.
- Prior Medications: Prior medications are defined as any medication where the use was stopped prior to the first administration of the study medication.
- Concomitant Medications: Concomitant medications are defined as any medication (other than the study vaccine) that was used at least once after the first administration of the study drug. Medications that were stopped on the same date as the first study drug administration will be defined as concomitant medications. If a clear determination cannot be made (partial medication end dates) the medication will be classified as concomitant
- Treatment Emergent Adverse Events (TEAEs) are defined as adverse events. that began after the start of an investigational product or an already present event that worsens either in intensity or frequency following the intervention.
- Duration of Adverse Events (AE) (days) is defined as: AE end date - onset of AE + 1.

3.3 Inferential Analyses

No formal hypothesis testing is planned.

Descriptive statistics will be used to summarize the safety and immunogenicity data.

3.4 Multiple Comparisons and Multiplicity Adjustments.

Not applicable for this study.

3.5 Handling of Missing Data

All collected and derived data will be included in the subject data listings. No imputations will be made for missing or incomplete data unless otherwise stated.

For the classification of Treatment emergent adverse event (TEAE) and Concomitant medication, the following will be applied in the following order:

a. If all dates/times (start and stop) are missing, the event/medication will automatically be classified as a TEAE/Concomitant medication.

b. For AEs with a missing start date/time, if the event end date/time is prior to first study drug administration, the event will not be classified as a TEAE.

c. If only the AE start year/ medication end year is present and is the same or is after the first study drug administration year unit, the event/medication will be classified as a TEAE/Concomitant medication.

d. If the AE start month and year/medication end month and year are present and are the same or after the first study drug administration month and year units, the event/medication will be classified as a TEAE/Concomitant medication.

For Immunogenicity quantitative data:
Immunological parameters below the Lower Limit Of Quantification (LLOQ) or the Limit Of Detection (LOD) (when available) will be imputed by half the lower limit of quantification or half the limit of detection for the descriptive summary. Immunological parameters above the Upper Limit of Quantification (ULOQ) will be imputed by multiplying by 2.

Such substitutions will be clearly documented in the footnotes of relevant outputs.

Missing immunogenicity results will not be replaced nor extrapolated.

Conversion of categorical values

In some instances, continuous variables are expressed as a range (i.e., < 10). In such cases, values may be converted to the range boundary (upper or lower limit as applicable). As an example, a value of <10 may be converted to 10. Such substitutions will be clearly documented in the footnotes of relevant outputs.

3.6 Coding of Events and Medications

Medical history and AE verbatim terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®) using the 26.1 available at the time of study commencement. Terms will be coded to the full MedDRA® hierarchy, but the system organ class (SOC) and preferred terms (PT) will be of primary interest for the analysis.

Prior and concomitant medications will be coded using the World Health Organization Drug Dictionary using the 26.1 available at the time of study commencement. Medications will be mapped to the full WHO-DD Anatomical Therapeutic Chemical (ATC) class hierarchy, but PTs will be of primary interest in this analysis.

3.7 Treatment arms

The following Treatment labels will be used for Summary Tables and Figures and Listings for the randomized population, the detailed dose of the treatment received will be given in footnote:

- Arm 1 (Medium dose)
- Arm 2 (High dose)
- Arm 3 (Placebo)
- Arm 1 + Arm 2
- Overall

4. ANALYSIS POPULATIONS

In this study 5 analysis populations are defined: Screened Analysis Set (ScS), Intent to Treat (ITT), Per Protocol Analysis Set (PPS), Safety Analysis Set (SAF) and Immunogenicity Analysis Set (IS).

Furthermore, any additional exploratory analysis not identified in the SAP will be identified in the final CSR as exploratory post hoc analyses, including analyses for additional study populations or subgroups of interest.

4.1 Population Descriptions

4.1.1 Screened Analysis Set (ScS)

All subjects who enter screening (assigned a screening number).

4.1.2 Intent to Treat (ITT)

All subjects who are randomized. The analyses using ITT will be based upon the randomization group allocated.

4.1.3 Per Protocol Analysis Set (PPS)

All subjects in the ITT set who receive one dose and who have not violated any inclusion/exclusion criteria and / or deviated in a way that could influence their Immunogenicity assessments.

4.1.4 Safety Analysis Set (SAF)

All randomized subjects who receive at least 1 dose of the study drug. Subjects will be analyzed according to the treatment (vaccine) they actually received. All safety analyses will be conducted based on the Safety set.

4.1.5 Immunogenicity Analysis Set (IS)

All randomized subjects who receive at least 1 dose of the study drug and have at least one valid immunogenicity result after Day 1. Subjects will be analyzed according to the treatment (vaccine) they actually received. All immunogenicity analyses will be conducted based on the Immunogenicity set.

5. SUBJECT DISPOSITION AND ANALYSIS POPULATIONS

Subject disposition and analysis population analysis will be based on ITT population. Subject disposition and analysis populations will be summarized descriptively as described in section 3.1 (categorical descriptive analysis).

5.1.1 Subject Disposition

Subject disposition will include the number of subjects who completed the study active period and treatment as planned, subjects withdrawn from the study active period and treatment, as well as the primary reason for early termination.

5.1.2 Analysis Populations

The number of subjects included in each study populations will be summarized descriptively. In addition, the inclusion of each subject into/from each of the defined analysis populations will be presented in the by-subject data listings.

6. PROTOCOL DEVIATIONS

Protocol deviations will be presented for each subject in the by-subject data listings.

Prior to database lock, all protocol deviations will be reviewed by medical monitors and assigned a status of Important if qualifying as such.

Protocol deviations and important protocol deviations will be categorized as noted in the Project Management Plan version 1.0 dated 30-AUG-2023.

7. DEMOGRAPHIC AND BASELINE INFORMATION

Demographic and baseline information analysis will be based on the Safety analysis set (SAF). Demographic and baseline information will be summarized descriptively as described in section 3.1 (Continuous/ Categorical data)

7.1 Demographics

The following demographic parameters will be analyzed:

Continuous descriptive analysis:

- Age (years)
- Height (cm)
- Weight (kg)
- BMI (kg/m^2)

Categorical descriptive analysis:

- Sex
- Childbearing Potential
- Race
- Ethnicity

All demographic parameters collected will be presented, for each treatment arm, in the by-subject data listings.

7.2 Medical /Surgical history

Medical / Surgical history will be coded using the latest MedDRA® version. All medical/surgical history as collected will be presented in the by-subject data listings and will be summarized by System Organ Class (SOC) and Preferred Term (PT) as described in section 3.1 (categorical data).

Subject who had multiple medical histories will be counted once in the specific category (SOC/ PT). SOC and PTs will be presented alphabetically. In addition to the summaries by the coded terms, the number of subjects with at least one medical history during the study will be presented.

All data collected will be presented, for each treatment arm, in the by-subject data listings.

7.3 Serology

Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus and Human Immunodeficiency Virus (HIV) results will be presented, for each treatment arm, in the by-subject data listings.

7.4 Urine Drug Screen

Urine Drug Test results will be presented, for each treatment arm, in the by-subject data listings.

7.5 Alcohol Test

Alcohol Test results obtained will be presented, for each treatment arm, in the by-subject data listings.

8. TREATMENT EXPOSURE

All study drug administration information (study drug administered (Yes/No), reason not administered, date and time of administration, dose format, study drug given as per protocol (Yes/No) and reason not given will be presented, for each treatment arm, in the by-subject data listings.

9. PRIOR AND CONCOMITANT MEDICATIONS

Concomitant medications will be summarized by Anatomical Therapeutic Chemical (ATC) class Level 3 and PT as noted in section 3.1 (categorical descriptive analysis) for Safety Analysis Set. Subjects who used the same medication on multiple occasions will only be counted once in the specific category (PT). PTs will be sorted alphabetically. In addition to the summaries by the coded terms, the number of subjects who used at least one concomitant medication during the study will be presented.

Prior and concomitant medications will be presented in the by-subject data listings.

10. PHARMACOKINETICS

No PK Analysis is planned for this study.

11. PHARMACODYNAMICS

No pharmacodynamic (PD) analysis is planned for this study.

12. EFFICACY

The exploratory efficacy analysis to assess the occurrence of acute gastroenteritis will be evaluated during the study period. The count and percentage of subject will be provided on safety population.

13. SAFETY

Safety endpoints will be analyzed using the SAF. Solicited Symptoms of Reactogenicity, unsolicited AEs, SAEs, and vital signs will be summarized descriptively by treatment arm (two active vaccine arms and placebo) and study day as described in section 3.1 (Categorical/Continuous).

Analyses will be performed for the total set (active vs. placebo).

SAEs will be categorized according to MedDRA® terms. The safety analyses are based on the safety set. Subjects will be summarized by vaccine arm and placebo according to the study drug they actually received. Missing reactogenicity Diary data will not be imputed; missing TEAE dates will be handled according to the rules determined in the SAP.

13.1 Solicited Symptoms of Reactogenicity

Solicited symptoms are predefined signs and symptoms of reactogenicity for which the subject is specifically questioned, and which are noted by the subject in their Solicited Symptom Diary, including:

- Fever (any temperature 100.4°F or higher)
- Headache
- Myalgia (muscle pain)
- Abdominal Pain
- Anorexia (defined and not eating)
- Nausea
- Vomiting
- Diarrhoea
- Malaise/Fatigue

Subjects will utilize a Solicited Symptom Diary issued on the day of the vaccination to record solicited symptom daily for one week (from Day 1 to Day 8) following that administration. After Day 8 solicited symptoms will be captured as unsolicited Adverse Events as descripted in section 13.2 with Day 8 as date of onset.

The count and percentage of subjects and the associated Clopper-Pearson 95% CIs reporting at least one solicited symptom during 8 days after vaccine administration (the 8 days include Day 1) will be summarized for each dose and presented by severity and cumulatively across severity levels as listed below:

- Grade 1 Solicited Symptoms
- Grade 2 Solicited Symptoms
- Grade 3 Solicited Symptoms
- Grade 4 Solicited Symptoms

where Grade 1 is mild, Grade 2 is moderate, Grade 3 is Severe, and Grade 4 is Potentially Life threatening as defined in Table 10 “Grading of Solicited Symptoms of Reactogenicity”.
Missing reactogenicity Diary data will not be imputed.

All the solicited symptoms collected during the active period of the study will also be presented for each treatment arm, study day, by severity in by-subject listing.

13.2 Unsolicited AE from Day 1 to Day 29 Post-Vaccination

An unsolicited AE is an observed AE that does not fulfill the conditions prelisted in the eCRF in terms of diagnosis and/or onset window post-vaccination; this also includes progression of chronic diseases. Unsolicited AEs includes both serious (SAEs) and non-serious unsolicited AE.

The unsolicited AE summaries will include:

- Overall summary of Unsolicited TEAEs that included at least one:
  - Unsolicited TEAEs

  - Grade ≥3 Unsolicited TEAEs
  - Related Unsolicited TEAEs
  - Grade ≥3 and Related Unsolicited TEAEs
  - Serious TEAE
  - Adverse Events of Special Interest (AESIs)
  - New Onsets of Chronic Illness (NOCIs)
  - Unsolicited TEAEs lead to study discontinuation
  - Unsolicited TEAEs result in death
- Unsolicited TEAEs summary by SOC and PT
- Grade ≥3 Unsolicited TEAEs summary by SOC and PT
- Related Unsolicited TEAEs summary by SOC and PT

The Grading of Severity of an TEAE is defined as:

- Grade 1 = mild
- Grade 2 = moderate
- Grade 3 = severe +/- life threatening

In the summary tables, the total number of subjects having reported at least one unsolicited AE with the proportion and the associated Clopper-Pearson 95% CIs, as well as the total number of AEs reported and the duration will be provided for each treatment arm. For example, the tables will state that X (%) subjects have reported Y events in the treatment arm A. Then, they will present the details of unsolicited AEs per SOC and PT with the same information: number (%) of subjects and number of events.

In the summary tables, unsolicited AEs will be presented by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each SOC and then similarly by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each PT.

Missing unsolicited TEAE dates will be handled according to the rules determined in section 3.1 (Date and time display conventions)

In addition, the duration of unsolicited TEAEs will be evaluated descriptively where subjects without AE are counted as missing.

All the unsolicited AEs collected during the active period of the study will also be provided for each treatment arm, study day, by severity and relationship to the treatment in by-subject listings. Separate listings will be done for subjects with TEAEs leading to study discontinuation, SAEs, AESIs, NOCIs and for Death events.

13.3 Serious Adverse Events

In the summary tables, the total number of subjects having reported at least one SAE with the proportion and the total number of SAEs reported will be provided for each treatment arm. For example, the tables will state that X (%) subjects have reported Y events in the treatment arm A. Then, they will present the details of SAEs per SOC and PT with the same information: number (%) of subjects and number of events.

The SAE summaries at Day 365 Post-Vaccination will include:

- SAEs summary by SOC and PT
- SAEs summary by SOC, PT and Severity
- SAEs summary by SOC, PT and Relationship

In the summary tables, SAEs will be presented by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each SOC and then similarly by decreasing

frequency of number of subjects with event and total events under "overall" treatment arm within each PT.

All SAEs collected during the follow-up period of the study will also be provided for each treatment arm, study day, in duration, by severity and relationship to the treatment in by-subject listings.

13.4 New Onset of Chronic Illness

New Onset of Chronic Illness (NOCI) is defined as diagnosis post-enrollment and vaccination of a new medical condition which is chronic in nature, including those potentially controllable by medication (e.g., diabetes, asthma).

In the summary tables, the total number of subjects having reported at least one NOCI with the proportion and the total number of NOCIs reported will be provided for each treatment arm. For example, the tables will state that X (%) subjects have reported Y events in treatment arm A. Then, they will present the details of NOCIs per SOC and PT with the same information: number (%) of subjects and number of events.

The NOCIs summaries at Day 365 Post-Vaccination will include:

- NOCIs summary by SOC and PT
- NOCIs summary by SOC, PT, and Severity
- NOCIs summary by SOC, PT and Relationship

In the summary tables, NOCIs will be presented by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each SOC and then similarly by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each PT.

All NOCIs collected during the follow-up period of the study will also be provided, for each treatment arm, study day, in duration, by severity and relationship to the treatment in by-subject listings.

13.5 Adverse Event of Special Interest

An adverse event of special interest (AESI) (serious or nonserious) is one of scientific and medical concern specific to the Sponsor's product or program, for which ongoing monitoring and rapid communication by the Investigator to the Sponsor can be appropriate. For this study, AESIs are serious or non-serious adverse events of scientific and medical concern with potential immune-mediated medical conditions as well as events associated with thrombosis and thrombocytopenia as listed in Table 11 in the protocol.

In the summary tables, the total number of subjects having reported at least one AESI with the proportion and the total number of AESIs reported will be provided for each treatment arm. For example, the tables will state that X (%) subjects have reported Y events in treatment arm A. Then, they will present the details of AESIs per SOC and PT with the same information: number (%) of subjects and number of events.

The AESIs summaries at Day 365 Post-Vaccination will include:

- AESIs summary by SOC and PT
- AESIs summary by SOC, PT, and Severity
- AESIs summary by SOC, PT and Relationship

In the summary tables, AESIs will be presented by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each SOC and then similarly by decreasing frequency of number of subjects with event and total events under "overall" treatment arm within each PT.

All AESIs collected during the follow-up period of the study will also be provided for each treatment arm, study day, in duration, by severity and relationship to the treatment in by-subject listings.

13.6 Vital Signs

The following vital signs measurements will be taken, in a sitting position, on the study day specified in the Schedule of activities:

- Systolic blood pressure (SBP) (mmHg)
- Diastolic blood pressure (DBP) (mmHg)
- Respiratory rate (breaths/min)
- Heart Rate (beats/min)
- Body Temperature (°F)
- Clinical Assessment for each vital sign measurement (as described below)

All vital signs data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

The parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Systolic Blood Pressure (mmHg)'. Parameters will be presented in the order defined above within the tables and listings.

Vital signs measurements will present summary statistics for observed values at baseline, each post-baseline and actual change from baseline (last pre-vaccination value) for each parameter and will be summarized as described in section 3.1 (continuous descriptive analysis).

The decimal precision to which the summaries for each displayed parameter will be based on the maximum number of decimals to which the results were reported on the eCRF.

The summary of all the clinical assessments for each parameter table will present counts and percentages for the reported results at baseline and each post-baseline visit/time point. Result categories will be ordered as 'Normal', 'Abnormal Not Clinically Significant (NCS)' and 'Abnormal Clinically Significant (CS)' (categorical descriptive analysis as described in section 3.1).

All individual Vital Signs results including unscheduled visits and their clinical assessment will be presented, for each treatment arm, by study days, in the by-subject listings.

13.7 Physical Examinations

Complete and symptom-directed physical examinations will be performed by the PI, on the study days specified in the schedule of activities.

Physical examinations may be performed at various unscheduled time points if deemed necessary.

By-subject data listings will be presented on the study days collected for complete physical examination parameters and Symptom directed physical examination parameters.

13.8 Pregnancy Test Results

A serum pregnancy test and a urine pregnancy test will be performed on the study day specified in the Schedule of activities.

All information related to pregnancy testing (urine and serum based) will be presented, for each treatment arm, by study days, in the by-subject data listings for all subjects.

14. IMMUNOGENICITY

Subjects will be analyzed according to the treatment (vaccine) they received. All immunogenicity analyses will be conducted based on the Immunogenicity Analysis set (IS).

Immunogenicity samples will be drawn for all subjects. Immunogenicity analyses will be based upon results from appropriately sized subsets of samples, according to the purpose. The statistical immunogenicity analysis will be primarily based on the evaluable Immunogenicity Analysis Set.

Vaccine induced immunogenicity will be evaluated in subject Breast Milk, serum, saliva, nasal secretions and in participants infants' stool samples. Samples will be collected from all subjects according to the time points specified in the SoA.

The following primary immunogenicity endpoints will be analyzed:

- Serum VP1 specific (GI.1 and GII.4) IgA through the active period measured by Meso Scale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8 and Day 29
    - Geometric mean fold rise (GMFR) from Day 1 to Day 8 and from Day 1 to Day 29
    - The number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint

- Breast Milk VPI specific (GI.1 and GII.4) IgA through the active period measured by MesoScale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8 and Day 29
    - Geometric mean fold rise (GMFR) from Day 1 to Day 8 and from Day 1 to Day 29
    - The number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in breast milk VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint

The following secondary immunogenicity endpoints will be analyzed:

- Serum VP1 specific (GI.1 and GII.4) IgA through 6 months after study drug dose measured by MesoScale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 180
    - Geometric mean fold rise (GMFR) from Day 1 to Day 180
    - The number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgG (GI.1 and GII.4) between Day 1 and Day 180
- Breast Milk VP1 specific (GI.1 and GII.4) IgA through 6 months after study drug dose measured by MesoScale Discovery (MSD) by dose level
    - Geometric mean concentration (GMC) at Day 60 and Day 180
    - Geometric mean fold rise (GMFR) from Day 1 to Day 60 and from Day 1 to Day 180
    - the number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint
- Serum VP1 specific (GI.1 and GII.4) IgG through 6 months after study drug dose measured by Meso Scale Discovery (MSD) assay by dose level
    - Geometric mean concentration (GMC) at Day 1, Day 8, Day 29, and Day 180
    - Geometric mean fold rise (GMFR) From Day to Day 8, from Day 1 to Day 29, and from Day 1 to Day 180
    - The number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMC rise or greater in serum VP1 specific IgA (GI.1 and GII.4) between Day 1 and any other timepoint
- Serum Blocking titers 50 (BT50) (GI.1 and GII.4) through 6 months after study drug dose measured by Histo-blood group antigen (HBGA) assay by dose level

- Geometric mean titer (GMT) at Day 1, and Day 29,
- Geometric mean fold rise (GMFR) from Day 1 to Day 29
- The number and %of subjects in each dose group that had a 2-fold, 3-fold and 4-fold GMT rise or greater in BT50 (GI.1 and GII.4) between Day 1 and Day 29

All the above analysis will be repeated for the per protocol set if the difference of sample size between per protocol and immunogenicity set are greater than 20%.

For the Exploratory samples: Saliva VP1 specific (GI.1 and GII.4) IgA, Nasal VP1 specific (GI.1 and GII.4) IgA, Infant stool VP1 specific (GI.1 and GII.4) IgA, Breast Milk Blocking titers 50 (BT50) (GI.1 and GII.4), and Breast Milk Enterocyte culture neutralizing antibody titers (GI.1 and GII.4) the results will be analyzed based on data availability and will be on file at Vaxart, Inc.

Statistical Method:

All immunogenicity data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

All results will be presented descriptively and summarized by treatment arms.

Definitions for GMC, GMT and Fold Rises

GMC = 10^[Σlog10(Ci)/N] where i = 1, 2, …, N

where N denotes the number of subjects within each treatment arm and Ci is the per subject immunogenicity concentration.

Fold Rise (Flr) = [CD8, CD29, CD60 or CD180]/[CD1].

CD8, CD29, CD60 and CD180 are the per subject immunogenicity concentration on Day 8, Day 29, Day 60, and Day 180 respectively.

CD1 = per subject immunogenicity concentration on Day 1 (pre-vaccination)

FIr is the fold rise per subject.

The fold change will be calculated per subject by dividing the concentration (original scale) on Day 8, 29, 60 and 180 with concentration at baseline (Day 1).

GMT = 10^[Σlog10(Ti)/N] where i = 1, 2, …, N

where N denotes the number of subjects within each treatment arm and Ti is the per subject immunogenicity titer.

Fold Rise (Flr) = [TD8, TD29 or TD180]/[TD1].

TD8, TD29 and TD180 are the per subject immunogenicity titers on Day 8, Day 29 and Day 180 respectively.

TD1 = per subject immunogenicity titers on Day 1 (pre-vaccination)

FIr is the fold rise per subject.

The fold change will be calculated per subject by dividing the titer (original scale) on Day 8, 29 and 180 with titer at baseline (Day 1).

≥x -Fold Rise represents the percentage of subjects with at least a x-Fold Rise compared to pre-vaccination dosing (Day 1), where x=2,3 and 4.

Geometric Mean Concentration (GMC) or Geometric Mean Titer (GMT) and Fold Change from Baseline

- Serum VP1 specific (GI.1 and GII.4) IgA, Serum VP1 specific (GI.1 and GII.4) IgG, GMCs with 95% CI, and their respective fold changes from baseline will be reported.
- Breast Milk VPI specific (GI.1 and GII.4) IgA GMCs with 95% CI, and their respective fold changes from baseline will be reported.
- Serum Blocking titers 50 (BT50) (GI.1 and GII.4), GMTs with 95% CI, and their respective fold changes from baseline will be reported.
- The 2-fold, 3-fold and 4-fold rise will be summarized for all the above immunogenicity endpoints.

Geometric means and its two-sided 95% Confidence Interval (CI) will be presented in original scale after back transformation of data.

Antibody responses over time will be shown graphically using a bar chart by the 2 active vaccine arms for:

- Serum VP1 specific (GI.1 and GII.4) IgA, Serum VP1 specific (GI.1 and GII.4) IgG with geometric mean concentration and their associated confidence intervals applied to the log transformed responses.
- Breast Milk VPI specific (GI.1 and GII.4) IgA with geometric mean concentration and their associated 95% confidence intervals applied to the log transformed responses.
- Serum antibody blocking titers 50 (BT50) (GI.1 and GII.4) with geometric mean titer and their associated 95% confidence intervals applied to the log transformed responses.

15. CHANGES TO THE PLANNED ANALYSIS

Changes to the planned analyses of the protocol and/or to the planned analyses from the SAP will be documented in the Statistical Report and in the Clinical Study Report (CSR).

Below is a description of changes made to the planned analysis for the Immunogenicity assessments:

- Calculation of 2-fold, 3-fold and 4-fold in GMCs and 2-fold, 3-fold and 4-fold in GMTs added in the primary and secondary immunogenicity endpoints.

Protocol Section(s), Description	Change in SAP
3.2.2. Immunogenicity Serum Blocking titers 50 (BT50) (GI.1 and GII.4) through 6 months after study drug dose measured by Histo-blood group antigen (HBGA) assay by dose level ▪ Geometric mean titer (GMT) at Day 1, Day 8, Day 29, and Day 180 ▪ Geometric mean fold rise (GMFR) from Day 1 to Day 8, from Day 1 to Day 29, and from Day 1 to Day 180	Serum Blocking titers 50 (BT50) (GI.1 and GII.4) through 6 months after study drug dose measured by Histo-blood group antigen (HBGA) assay by dose level ▪ Geometric mean titer (GMT) at Day 1 and Day 29 ▪ Geometric mean fold rise (GMFR) from Day 1 to Day 29

16. INTERIM AND FINAL ANALYSIS

A principal statistical analysis will be performed after all subjects have completed the active period of the study up to Day 29 post-vaccination, the subject database has been locked, the analysis set of populations will be approved, and the study will be unblinded except the medical monitoring and pharmacovigilance team including anyone at the Sponsor, CRO and sites(s). The principal Clinical Study Report (CSR) will be written after this analysis. If any exploratory parameters are available, Vaxart will keep them for possible future analysis. A final statistical analysis will be performed after all subjects have completed the long-term follow-up phase of the study up to Day 365 post-vaccination and safety dataset has been locked. An addendum to the principal CSR will be written after this analysis.

The final analysis will be based on the final version of SAP.

17. SOFTWARE

- SAS® Version 9.4 or higher (SAS Institute, Cary, North Carolina, USA).

18. TABLES

Table Number	Table Title	Population
14.1	**Demographics and Other Baseline Characteristics**	
14.1.1	Summary of Subject Enrolment and Disposition by Treatment arm	ScS
14.1.2	Summary of Demographics and Baseline Characteristics by Treatment arm	Safety
14.1.3	Summary of Medical/Surgical History by System Organ Class, Preferred Term and Treatment arm	Safety
14.2	**Immunogenicity**	
14.2.1.1	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise from Baseline at Day 8 by Treatment Arm	Immunogenicity
14.2.1.1a	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise from Baseline at Day 8 by Treatment Arm	Per Protocol
14.2.1.2	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 29, by Treatment Arm	Immunogenicity
14.2.1.2a	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 29, by Treatment Arm	Per Protocol
14.2.1.3	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise from Baseline at Day 180 by Treatment Arm	Immunogenicity
14.2.1.3a	Summary of Serum VP1 Specific GI.1 and GII.4 IgA (AU/mL) Geometric Mean Concentration and Fold Rise from Baseline at Day 180 by Treatment Arm	Per Protocol
14.2.2.1	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 8 by Treatment Arm	Immunogenicity
14.2.2.1a	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 8 by Treatment Arm	Per Protocol
14.2.2.2	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 29 by Treatment Arm	Immunogenicity
14.2.2.2a	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 29 by Treatment Arm	Per Protocol
14.2.2.3	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 60 by Treatment Arm	Immunogenicity
14.2.2.3a	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 60 by Treatment Arm	Per Protocol
14.2.2.4	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 180 by Treatment Arm	Immunogenicity

Table Number	Table Title	Population
14.2.2.4a	Summary of Breast Milk VP1 Specific GI.1 and GII.4 IgA (RLU/ug of total IgA) Geometric Mean Concentration and Fold Rise from Baseline at Day 180 by Treatment Arm	Per Protocol
14.2.3.1	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 8, by Treatment Arm	Immunogenicity
14.2.3.1a	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 8, by Treatment Arm	Per Protocol
14.2.3.2	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 29, by Treatment Arm	Immunogenicity
14.2.3.2a	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 29, by Treatment Arm	Per Protocol
14.2.3.3	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 180, by Treatment Arm	Immunogenicity
14.2.3.3a	Summary of Serum VP1 Specific GI.1 and GII.4 IgG (AU/mL) Geometric Mean Concentration and Fold Rise, from Baseline at Day 180, by Treatment Arm	Per Protocol
14.2.4.1	Summary of Serum GI.1 and GII.4 Blocking Titers 50 (BT50) Geometric Mean Titer and Fold Rise, from Baseline at Day 29, by Treatment Arm	Immunogenicity
14.2.4.1a	Summary of Serum GI.1 and GII.4 Blocking Titers 50 (BT50) Geometric Mean Titer and Fold Rise, from Baseline at Day 29, by Treatment Arm	Per Protocol
14.3	**Safety**	
14.3.1	Summary of Concomitant Medications by ATC Class, Preferred Name and Treatment arm.	Safety
14.3.3	**Adverse Events**	
14.3.3.1.1	Summary of Solicited Symptoms of Reactogenicity Post-Vaccination by Treatment arm	Safety
14.3.3.1.2	Summary of Solicited Symptoms of Reactogenicity continuing beyond Day 8 Post-Vaccination by Treatment arm	Safety
14.3.3.1.3	Summary of Solicited Symptoms of Reactogenicity by Treatment Arm and by Severity from Day 1 to Day 8 Post-Vaccination	Safety
14.3.3.1.4	Summary of Overall Unsolicited Treatment Emergent Adverse Events by Treatment arm, from Day 1 to Day 29 Post-Vaccination.	Safety
14.3.3.1.5	Summary of duration (in days) of Overall Unsolicited Treatment Emergent Adverse Events by Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.6.1	Summary of Unsolicited Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.6.2	Summary of Unsolicited Treatment Emergent Adverse Events by System Organ Class, Preferred Term, Severity and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety

Table Number	Table Title	Population
14.3.3.1.6.3	Summary of Unsolicited Treatment Emergent Adverse Events by System Organ Class, Preferred Term, Relationship and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.7.1	Summary of Serious Adverse Events by System Organ Class, Preferred Term and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.7.2	Summary of Serious Adverse Events by System Organ Class, Preferred Term, Severity and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.7.3	Summary of Serious Adverse Events by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.7.4	Summary of Serious Adverse Events by System Organ Class, Preferred Term and Treatment Arm, From Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.7.5	Summary of Serious Adverse Events by System Organ Class, Preferred Term, Severity and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.7.6	Summary of Serious Adverse Events by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.8.1	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.8.2	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term, Severity and Treatment arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.8.3	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.8.4	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.8.5	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term, Severity and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.8.6	Summary of New Onset of Chronic Illness by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.9.1	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term and Treatment Arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.9.2	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term, Severity and Treatment Arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.9.3	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 1 to Day 29 Post-Vaccination	Safety
14.3.3.1.9.4	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety

Table Number	Table Title	Population
14.3.3.1.9.5	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term, Severity and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.3.1.9.6	Summary of Adverse Event of Special Interest by System Organ Class, Preferred Term, Relationship and Treatment Arm, from Day 30 to Day 365 Post-Vaccination	Safety
14.3.5	**Other Safety**	
14.3.5.1.1	Summary of Vital Signs by Treatment arm	Safety
14.3.5.1.2	Summary of Clinical Assessments of Vital Signs by Treatment arm	Safety

19. LISTINGS

Listing Number	Listing Title	Population
16.2.1	**Subject Disposition**	
16.2.1.1	Analysis Populations by Treatment arm	ScS
16.2.1.2.1	Subject Disposition by Treatment arm from Day 1 to Day 29	ITT
16.2.1.2.2	Subject Disposition by Treatment arm from Day 30 to Day 365	ITT
16.2.2	**Protocol Deviations**	
16.2.2.1	Protocol Deviations by Treatment arm	ITT
16.2.4	**Demographic and Other Baseline Data**	
16.2.4.1	Demographics and Baseline Characteristics by Treatment arm	Safety
16.2.4.1.a	Demographics and Baseline Characteristics (Infant) by Treatment arm	Safety
16.2.4.2	Medical/Surgical History	Safety
16.2.4.2.a	Vaccination Status	Safety
16.2.4.2.b	Infant Health	Safety
16.2.4.3	Urine Drug Screen	Safety
16.2.4.4	Alcohol Test	Safety
16.2.4.5	Serology	Safety
16.2.4.6.1	Eligibility Criteria	ScS
16.2.4.6.2	Screen Failure Subjects	ScS
16.2.5	**Treatment Administration**	
16.2.5.1	Subject Randomization by Treatment arm	ITT
16.2.5.2	Study Drug Administration by Treatment arm	ITT
16.2.6	**Immunogenicity**	
16.2.6.1	Serum VP1 Specific GI.1 IgA (AU/mL) Concentration by Treatment Arm	Immunogenicity
16.2.6.2	Serum VP1 Specific GII.4 IgA (AU/mL) Concentration by Treatment Arm	Immunogenicity
16.2.6.3	Breast Milk VP1 Specific GI.1 IgA (RLU/ug of total IgA) Concentration by Treatment Arm	Immunogenicity
16.2.6.4	Breast Milk VP1 Specific GII.4 IgA (RLU/ug of total IgA) Concentration by Treatment Arm	Immunogenicity
16.2.6.5	Serum VP1 Specific GI.1 IgG (AU/mL) Concentration by Treatment Arm	Immunogenicity
16.2.6.6	Serum VP1 Specific GII.4 IgG (AU/mL) Concentration by Treatment Arm	Immunogenicity
16.2.6.7	Serum GI.1 Blocking Titers 50 (BT50) by Treatment Arm	Immunogenicity

Listing Number	Listing Title	Population
16.2.6.8	Serum GII.4 Blocking Titers 50 (BT50) by Treatment Arm	Immunogenicity
16.2.7	**Adverse Events**	
16.2.7.1	Solicited Symptoms reported between Day 1 to Day 8, by Treatment Arm	Safety
16.2.7.2	Solicited Symptoms Diary Card with Severity Grading, by Treatment Arm	Safety
16.2.7.3	Unsolicited Adverse Events reported between Day 1 to Day 29, by Treatment Arm	Safety
16.2.7.4.1	Serious Adverse Events reported between Day 1 to Day 29, by Treatment Arm	Safety
16.2.7.4.2	Serious Adverse Events reported between Day 30 to Day 365, by Treatment Arm	Safety
16.2.7.5.1	Adverse Event of New Onset Chronic Illness reported between Day 1 to Day 29, by Treatment Arm	Safety
16.2.7.5.2	Adverse Event of New Onset Chronic Illness reported between Day 30 to Day 365, by Treatment Arm	Safety
16.2.7.6.1	Adverse Event of Special Interest reported between Day 1 to Day 29, by Treatment Arm	Safety
16.2.7.6.2	Adverse Event of Special Interest reported between Day 30 to Day 365, by Treatment Arm	Safety
16.2.7.7.1	Unsolicited TEAEs related to study drug Day 1 through Day 29, by Treatment Arm	Safety
16.2.7.8.1	Death event reported between Day 1 to Day 29, by Treatment Arm	Safety
16.2.7.8.2	Death event reported between Day 30 to Day 365, by Treatment Arm	Safety
16.2.8	**Other Safety**	
16.2.8.1	Vital Signs by Treatment arm	Safety
16.2.8.2	Physical Examination by Treatment arm	Safety
16.2.8.3	Pregnancy Test Results by Treatment arm	Safety
16.2.9	**Prior & Concomitant Medication**	
16.2.9.1	Prior Medication by Treatment arm	Safety
16.2.9.2	Concomitant Medication by Treatment arm	Safety
16.2.9.3	Surgical and Medical Procedure	Safety
16.2.9.3.a	Surgical and Medical Procedure (Infant)	Safety

20. FIGURES

Figure Number	Figure Title	Population
14.2	**Immunogenicity**	
14.2.1.1	Serum VP1 specific GI.1 IgA Geometric Mean Concentration Bar Plot Over Time by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.1.2	Serum VP1 specific GI.1 IgA Geometric Mean Concentration Bar Plot Over Time by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.2.1	Serum VP1 specific GII.4 IgA Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.2.2	Serum VP1 specific GII.4 IgA Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.3.1	Breast Milk VP1 specific GI.1 IgA Geometric Mean Concentration Bar Plot Over Time by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.3.2	Breast Milk VP1 specific GI.1 IgA Geometric Mean Concentration Bar Plot Over Time by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.4.1	Breast Milk VPI specific GII.4 IgA Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.4.2	Breast Milk VPI specific GII.4 IgA Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.5.1	Serum VP1 specific GI.1 IgG Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.5.2	Serum VP1 specific GI.1 IgG Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.6.1	Serum VP1 specific GII.4 IgG Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.6.2	Serum VP1 specific GII.4 IgG Geometric Mean Concentration Bar Plot, by Treatment Arm, between Day 1 to Day 180	Immunogenicity
14.2.7.1	Serum Blocking Titers 50 (BT50) GI.1 IgG Geometric Mean Titer Bar Plot, by Treatment Arm, between Day 1 to Day 29	Immunogenicity
14.2.8.1	Serum Blocking Titers 50 (BT50) GII.4 IgG Geometric Mean Titer Bar Plot Over Time by Treatment Arm, between Day 1 to Day 29	Immunogenicity

21. REFERENCES

1) VXA-NVV-108 Study Protocol Version *2.0* dated *25 July 2023*.
2) VXA-NVV-108_Protocol Clarification Memorandum #2_24 Jan 2024 signed.

[redacted]

Note to File

Study title: Evaluating Vaxart's oral bivalent GI.1/GII.4 norovirus vaccine in healthy lactating females and their nursing infants

Protocol Number: VXA-NVV-108

Date: November 14, 2024

Subject: Errata note to file Regarding AE of Hypertension in Subject [redacted] Detected After Database Lock (DBL)

Description: During an Interim Monitoring Visit (IMV) in July 2024 at site 2303, the CRA identified a new record for subject [redacted] documenting an adverse event (AE) of hypertension. This AE had originally been detected by the site on January 5, 2024, while the subject was still in the active study period. However, the site missed entering it into the eCRF. When the CRA discovered the AE, the database had already been locked for the active study portion, preventing the AE from being added.

This note has b[redacted]

Root Cause: T[redacted]

Impact: The is[redacted]be mentioned in t[redacted]es (TLFs) or in-te[redacted]fety analysis, as the[redacted]AE was considered[redacted]nted in the printed AE page of the EDC.

Attachments: printed eCRF AE pages completed the site.

[redacted]

Vaxart Inc

[redacted]

[redacted]

VXA-NVV-108_V3.0_PK_06DEC2023_PROD: Unique
Project Name: VXA-NVV-108
Form: Adverse Events Summary
Generated On: 07 Feb 2024 04:35:28

Did the Subject experience any Adverse Events during the Study?	Yes [redacted] No ◯

VXA-NVV-108_V3.0_PK_06DEC2023_PROD: Unique
Project Name: VXA-NVV-108
Form: Adverse Events
Generated On: 07 Feb 2024 04:35:28

Adverse Event Term [redacted]
Start Date (dd- MMM- yyyy)
Start Time
Fixed Unit: 24-hour clock

AE Start Time Unknown [redacted]
Tick if the AE is Ongoing
End Date (dd- MMM- yyyy)
End Time
Fixed Unit: 24-hour clock

AE End Time Unknown [redacted]
Severity
Mild
Moderate
Severe

Is this Solicited Symptom related to IP? [redacted]
Yes
No

Relationship to study treatment
Definite ☐
Possibly ☐
Potential ☐
Unlikely ☐
Not related [redacted]

Did the adverse event lead to study discontinuation? [redacted]
Yes ☐
No

Outcome
Recovered/Resolved ☐
Recovering/Resolving ☐
Recovered/Resolved with Sequelae ☐
Not Recovered/Not Resolved ☐
Fatal ☐
Unknown [redacted]

Was this reported as a solicited symptom in the diary? [redacted]
Yes
No

VXA-NVV-108_V3.0_PK_06DEC2023_PROD: Unique
Project Name: VXA-NVV-108
Form: Adverse Events
Generated On: 07 Feb 2024 04:35:28

Was a concomitant or additional treatment given due to this adverse event?	Yes ☐ No [redacted]
If Yes, please select the corresponding Concomitant Medication#1	
Concomitant Medication #2	
Concomitant Medication #3	
Concomitant Medication #4	
Concomitant Medication #5	
What action was taken with study treatment?	Dose Increased ☐ Dose Not Changed ☐ Dose Reduced ☐ Drug Interrupted ☐ Drug Withdrawn ☐ Dose Rate Reduced ☐ Not Applicable [redacted] Unknown
Was any other action taken?	Yes [redacted] No ☐
If Yes, specify	[redacted]
Is Adverse Event of Special Interest?	Yes ☐ No [redacted]
Is Adverse Event of New Onset Chronic Illness (NOCI)?	Yes No
Is the Adverse Event Serious?	Yes No
Is the adverse event life threatening?	Yes No
Did the adverse event result in initial or prolonged hospitalization for the patient?	Yes No
Date of Admission (dd- MMM- yyyy)	[redacted]
Date of Discharge (dd- MMM- yyyy)	

VXA-NVV-108_V3.0_PK_06DEC2023_PROD: Unique
Project Name: VXA-NVV-108
Form: Adverse Events
Generated On: 07 Feb 2024 04:35:28

Did the adverse event result in persistent or significant disability or incapacity?	Yes No
Is the adverse event associated with other serious or important medical events?	Yes No
Is the adverse event associated with a congenital anomaly or birth defect?	Yes No
Did the adverse event result in death?	Yes No
AE Start Date/Time (Derived)	[redacted]
AE End Date/Time (Derived)	

[redacted]

vxa pt 2303-003 sample case report form

Final Audit Report 2024-11-21

Created:	2024-11-15
By:	[redacted]
Status:	Signed
Transaction ID:	[redacted]

"vxa pt 2303-003 sample case report form" History

Document created by [redacted]
2024-11-15 - 6:21:49 AM GMT- IP address: [redacted]

Document emailed to [redacted] for signature
2024-11-15 - 6:22:34 AM GMT

Email viewed by [redacted]
2024-11-21 - 6:59:51 AM GMT- IP address: [redacted]

[redacted] authenticated with Email OTP by verifying one-time code sent via email
Challenge: The user completed the signing ceremony.
2024-11-21 - 7:05:00 AM GMT

Signer [redacted] entered name at signing as [redacted]
2024-11-21 - 7:05:01 AM GMT- IP address: [redacted]

Document e-signed by [redacted]
Signing reason: I approve
Signature Date: 2024-11-21 - 7:05:03 AM GMT - Time Source: server- IP address: [redacted]

Agreement completed.
2024-11-21 - 7:05:03 AM GMT