Statistical Analysis Plan
for
Final Analysis

Version 1.0

March 12, 2020

Trial Registration Reference: NCT03703336 (ClinicalTrials.gov)

Protocol Number

CVIA 068

Title

A Phase III, Randomized, Partially Double-Blind, Active Control Study to Compare the Immunogenicity and Safety of a Liquid Formulation of ROTAVIN with the currently Licensed Frozen Formulation of the Vaccine (ROTAVIN-M1), in Healthy Vietnamese Infants.

Sponsored by

Center for Research and Production of Vaccines and Biologicals (POLYVAC), Vietnam
In Collaboration with PATH, USA

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Sponsor:	Center for Research and Production of Vaccines and Biologicals (POLYVAC), Vietnam In Collaboration with PATH, USA
Clinical Trial Operational Oversight	**Manufacturer and Sponsor:** POLYVAC Center for Research and Production of Vaccines and Biologicals 135 Lo Duc Street, Hai Ba Trung District, Hanoi, Vietnam. **Collaborator and Funder:** PATH 2201 Westlake Avenue, Suite 200 Seattle, WA 98121, USA **CRO** Emmes Services Pvt. Ltd. (Emmes) Unit #2, First Floor, Indiqube ETA 38/4, Doddanekundi, Outer Ring Road, Bangalore-560048, India
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SIGNATURE PAGE

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PROTOCOL NUMBER: CVIA 068

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LIST OF ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
ATC	Anatomical Therapeutic Chemical
°C	Degrees Celsius
CCHMC	Cincinnati Children's Hospital Medical Center
CI	Confidence Interval
cm	Centimeter
CRF	Case Report Form
CRO	Contract Research Organization
D	Day
DSMB	Data and Safety Monitoring Board
DTP	Diphtheria, Tetanus and Pertussis
DTwP	Diphtheria, Tetanus, Pertussis (whole cell)
ELISA	Enzyme-Linked Immunosorbent Assay
EPI	Expanded Program on Immunization
FA	Full Analysis
GCP	Good Clinical Practice
GMC	Geometric Mean Concentration
HepB	Hepatitis B
Hib	*Haemophilus influenzae type b*
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
IgA	Immunoglobulin A
IP	Investigational Product
IU	International Unit
kg	Kilogram
LAR	Legally Acceptable Representative
LLOQ	Lower Limit of Quantitation
MedDRA	Medical Dictionary for Regulatory Activities
mL	Milliliter
N	Number (typically refers to number of participants)
NICVB	National Institute for Control of Vaccine and Biologicals
NIHE	National Institute of Hygiene and Epidemiology
OPV	Oral Polio Vaccine
PE	Physical Examination
PFU	Plaque Focus Unit
PI	Principal Investigator
PIDC	Post-Immunization Diary Card
POLYVAC	Center for Research and Production of Vaccines and Biologicals
PP	Per Protocol
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
SRC	Safety Review Committee
SD	Standard Deviation
ULOQ	Upper Limit of Quantitation
USA	United States
WHO	World Health Organization
V	Visit number

1. Introduction

This Statistical Analysis Plan (SAP) describes all planned analyses for the final statistical report for "A Phase III, Randomized, Partially Double-Blind, Active Control Study to Compare the Immunogenicity and Safety of a Liquid Formulation of ROTAVIN with the currently Licensed Frozen Formulation of the Vaccine (ROTAVIN-M1®), in Healthy Vietnamese Infants." (Protocol CVIA 068). This document expands upon the statistical information presented in the protocol for these analyses and provides reasons and justifications for these analyses. It also includes corresponding sample shells (or templates) tables, listings, and figures.

This SAP is consistent with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials).

This document contains five parts:

a) A review of the study objectives and design including sample size considerations: sections 2 through 5,

b) Description of the interim analyses and Data and Safety Monitoring Board (DSMB) safety reviews: section 6

c) General statistical considerations: section 7,

d) Comprehensive statistical analysis methods for the final analysis: sections 8 through 14,

e) A list of proposed shells for tables, listings and figures: section 15.

Any deviation from this SAP will be identified, described and justified in the corresponding statistical reports and final clinical study report. The reader of this SAP is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

2. Study Rationale

ROTAVIN-M1® was developed to provide an affordable vaccine for Vietnamese children for the protection of rotavirus which is the leading cause of severe diarrhea. ROTAVIN-M1® is the frozen formulation of the vaccine which needs to be stored and transported at -20°C. ROTAVIN-M1® was approved by NICVB for production in 2007 and it was licensed in May 2012. POLYVAC the manufacturer of ROTAVIN-M1® has also been working on a second generation formulation which may be more stable and can be stored at 2-8°C (liquid formulation of ROTAVIN) through the entire shelf life which will widen its usability and make it more suitable for programmatic application.

3. Study Objectives and Endpoints

3.1 Study Objectives

3.1.1 Primary Objectives

Immunogenicity

To demonstrate non-inferiority in the immunogenicity of the liquid formulation of ROTAVIN in comparison to currently licensed frozen formulation of the Vaccine (ROTAVIN-M1®), 28 days after

the last dose of the vaccine when administered to infants in a two-dose schedule starting at 60-91 days of age.

Safety

To evaluate the safety of liquid formulation of ROTAVIN in comparison with currently licensed frozen formulation (ROTAVIN-M1®), in terms of solicited reactions after each dose of vaccine.

3.1.2 Secondary Objectives

Immunogenicity

To further characterize the immunogenicity of the liquid formulation of ROTAVIN in comparison with currently licensed frozen formulation of the vaccine (ROTAVIN-M1®).

Safety

To evaluate the safety of the liquid formulation of ROTAVIN in terms of immediate post-vaccination events, unsolicited adverse events and serious adverse events, including monitoring for intussusception

3.2 Study Endpoints

3.2.1 Primary Endpoints

Immunogenicity

Rotavirus vaccine immunogenicity will be tested on serum samples obtained in a subset of 450 participants before the first vaccination and four weeks after the second vaccination using a validated ELISA assay. The primary immunogenicity endpoint is as follows:

- Geometric mean concentration (GMC) of serum anti-rotavirus IgA antibody concentrations 28 days after the second vaccination.

Safety

Solicited post-vaccination reactogenicity (fever, diarrhea, vomiting, decreased appetite, irritability, and decreased activity level) during the 7 day period (Day 1-7) after each vaccination.

3.2.2 Secondary Endpoints

Immunogenicity

- Percentage of participants with seroconversion in serum anti-rotavirus IgA antibody concentrations 28 days after the second vaccination defined as follows:
  - For participants with a negative pre-vaccination IgA concentration (< 20 IU/ml), a positive post-vaccination IgA concentration (≥ 20 IU/ml);
  - For participants with a positive pre-vaccination IgA concentration, a post-vaccination IgA concentration at least 4 times as high as the pre-vaccination IgA concentration.
- Percentage of participants with seropositivity at baseline and 28 days after the second vaccination. Seropositivity is defined as serum IgA antibody concentration ≥ 20 IU/ml.

Safety

- Immediate adverse events, within 30 minutes after each vaccination.
- Unsolicited AEs from vaccination through four weeks after each dose.
- Serious adverse events (SAEs) and intussusception from first vaccination through four weeks after the last vaccination.

4. Investigational Plan

4.1 Overall Study Design and Plan

The study is designed as a phase III, multicenter, randomized, partially double-blinded, active controlled study enrolling 825 infants 60-91 days of age. The objective of the study is to compare the safety and immunogenicity of the liquid formulation of ROTAVIN with already licensed vaccine ROTAVIN-M1®.

The study will be conducted at commune health centers in Nam Dinh and Quang Ninh provinces in Vietnam. Prospective participants, whose parent or legal guardian sign an informed consent form will be assessed for eligibility to participate in the study. Screening for eligibility will include solicitation of medical history, assessment of vital signs and physical examination. If the participant is found to be eligible, the infants will be allocated to one of the two groups at a ratio of 2:1 to receive the study vaccine with 550 participants receiving the liquid formulation of ROTAVIN and 275 participants receiving the frozen formulation (ROTAVIN-M1®). The study will be conducted according to a partially blinded study design in which the vaccine administrator will be considered unblinded whereas the parents, and rest of the study team including endpoint assessor will be blinded to the treatment received by the child. Two doses of vaccine will be administered 8 (+2) weeks apart (minimum interval of 8 weeks and maximum of 10 weeks), with the first administration given at 60-91 days of age (both days inclusive). Childhood vaccines as per the Expanded Program for Immunization (EPI) of the Government of Vietnam will not be allowed within 7 days before or after study vaccine administration.

To evaluate the Rotavirus vaccine immunogenicity, blood samples will be obtained from all the participating infants from Quang Ninh site before the first vaccination and four (+2) weeks after the second vaccination. Immunogenicity will be assessed in all infants who provided blood samples at the selected site. Serum Anti-rotavirus IgA antibodies will be analyzed at Cincinnati Children's Hospital Medical Center (CCHMC), Cincinnati, Ohio, USA using a validated ELISA which uses strain 89-12 as a substrate.

Vaccinated participants will be observed for immediate adverse events for 30 minutes after each vaccination. Active surveillance for vaccine reactogenicity (solicited reactions) over the 7-day period after each vaccination, unsolicited AEs for 4 weeks after each vaccination and SAEs including intussusception over the period between first vaccination and four weeks after the last vaccination will be conducted for all infants.

This study will have extensive safety monitoring in place. At the performing site level, the study site investigators and their clinical staff will be responsible for continuous close safety monitoring of all study participants and for alerting the protocol team if unexpected concerns arise. A team of vaccine experts, Safety Review Committee (SRC) composed of a group of physicians, which include but not limit to the designated investigator from study team and the Medical Officer(s)

from POLYVAC and PATH, a Pharmacovigilance/Medical officer from the CRO and an independent vaccine expert will be closely following the study for safety oversight. The SRC may seek independent expert medical opinion as dictated by the occurrence of certain events.

The SRC will have provision of expedited meeting that could be triggered by reporting of predefined AEs. The SRC may also seek independent expert medical opinion as dictated by the occurrence of certain events.

The schedule of study assessments is given in Table A1 below.

Table A1: Trial Schema- Schedule of Events

Visit	V1*		V2*	V3
Time point (Day)	D1		D57	D85
Interval (window period)	Screening	Post enrollment	V1+ 8 (+2) weeks	V2+ 4 (+2) weeks
Information process and written informed consent	X			
Collect baseline demographic data	X			
Collect/review medical history	X			
Perform Physical examination and Vital examination	X[a]		X	X
Check inclusion/exclusion criteria	X			
Enrollment	X			
Randomization		X		
Collect blood for immunogenicity assessment[b]		X (Pre-dose)		X
Check withdrawal criteria			X	X
Check contraindications, warnings and precautions to vaccine administration			X	
Study vaccination		X	X	
Observe for immediate reactions for 30 minutes		X	X	
Perform post-vaccination Vital examination and targeted physical examination if required.		X	X	
Issue and instruct parent/LAR of participant on use of diary card		X	X	
Record solicited AEs within 7 days post vaccination		X	X	
Safety follow-up by health worker[c]		X	X	
Record unsolicited AEs, including SAEs		X	X	X
Record any concomitant medications/vaccinations		X	X	X
Review interim medical history and record any intercurrent medical conditions			X	X
Participant completion of study				X

D = day; AE = adverse events; SAE = serious adverse event; Shading represents days of vaccination; V=Visit number.

* The study visits will be planned in advance such that the EPI vaccination days fall either more than 7 days before or after the study vaccination day. This will allow the participant to receive EPI vaccines in the window allowed by the protocol.

[a] Symptom based physical examination to be performed if screening is being repeated and there is any change in health since last screening.

[b] At Quang Ninh site

[c] This includes visit by the health worker to the participant's home on Day 2/58 (+1) and 8/64 (+2) after each vaccination and a telephone call on Day 5/61 (+2).

4.2 Selection of Study Population

Approximately 825 healthy male and female infants, 60-91 days of age will be enrolled in the study from the two provinces in Vietnam.

Participant Inclusion Criteria

The following criteria must be met before a participant may be enrolled for participation:

1. Healthy infants as established by medical history and clinical examination before entering the study.
2. Age: 60-91 days (both days inclusive) at the time of enrollment.
3. Parental/Legally Acceptable Representative (LAR) ability and willingness to provide written informed consent.
4. Parent/LAR who intends to remain in the area with the child during the study period.

Participant Inclusion Criteria

Participants meeting any of the temporary exclusion criteria can be rescreened for eligibility at a later time and enrolled if eligible at that time.

Participants meeting any of the following criteria will be excluded from participation:

1. Presence of diarrhea or vomiting in the previous 72 hours or on the day of enrollment (temporary exclusion).
2. Presence of fever on the day of enrollment (temporary exclusion).
3. Acute disease at the time of enrollment (temporary exclusion).
4. Concurrent participation in another clinical trial at any point throughout the entire timeframe for this study.
5. Presence of significant malnutrition (weight-for-height z-score < -3SD median).
6. Presence of any systemic disorder (cardiovascular, pulmonary, hepatic, renal, gastrointestinal, hematological, endocrine, immunological, dermatological, neurological, cancer, or autoimmune disease) as determined by medical history and / or physical examination which would compromise the participant's health or is likely to result in nonconformance to the protocol.
7. History of congenital abdominal disorders, intussusception, or abdominal surgery.
8. Known or suspected impairment of immunological function based on medical history and physical examination.
9. Household contact with an immunosuppressed individual or pregnant woman.
10. Prior receipt of rotavirus or an intent to receive this vaccine from outside of the study center during study participation.
11. Prior receipt of EPI vaccination during past 7 days or plan to receive them within next 7 days.

12. A known sensitivity or allergy to any components of the study vaccine.
13. History of allergy to antibiotic kanamycin.
14. Clinically detectable significant congenital or genetic defect.
15. History of persistent diarrhea (defined as diarrhea that lasts 14 days or longer).
16. Receipt of immunoglobulin therapy and / or blood products since birth or planned administration during the study period.
17. History of chronic administration (defined as more than 14 days) of immunosuppressants including corticosteroids. Infants on inhaled or topical steroids may be permitted to participate in the study.
18. Any medical condition in the parent/LAR or infant which, in the judgment of the Investigator, would interfere with or serves as a contraindication to protocol adherence.

4.3 Treatment

4.3.1 Treatments Administered

The treatments administered are:

1. **Test Vaccine – ROTAVIN liquid formulation:** This is a live attenuated human rotavirus vaccine (rotavirus strain G1P[8]) at a dosage of ≥ 2x 10^6 plaque focus units (PFU) / dose of 2 ml. The vaccine can be stored and transported at 2-8°C. The vaccine is for oral use. ROTAVIN liquid formulation has a sterile, yellow, clear liquid, free of visible particles, to be used after shaking well.
2. **Comparator Vaccine – ROTAVIN-M1®:** Live Attenuated human rotavirus vaccine(rotavirus strain G1P[8]) at a dosage of ≥ 2x10^6 plaque focus units (PFU) / dose of 2 ml. The vaccine is for oral use. ROTAVIN liquid formulation has a sterile, pink clear liquid, free of visible particles, to be used after shaking well.

   This frozen vaccine vial will be stored at -20°C. The vaccine can also be stored and transported at 2-8°C up to 2 months. For this study ROTAVIN-M1® will be supplied monthly by the manufacturer with storage and transport at 2-8°C at the site.

4.3.2 Method of Assigning Participants to Vaccine groups (Randomization)

The study will be conducted in the Nam Dinh and Quang Ninh provinces in Vietnam. Randomization and all study related activities will take place at approximately 12 commune health centers associated with one of the sites, and not at the sites. Within each site, the commune health centers will be divided into two independent teams, Team 1 and Team 2.

A manual randomization process will be used. Randomization will be stratified by site and team using a permuted block design. The unblinded team at the CRO will create two sealed opaque envelopes for each participant. When an infant is randomized, the seal of the envelope infant's participant ID is broken, and the vaccine with the code given inside the envelope is administered to the participant by the unblinded vaccine administrator. After vaccination, the envelope will be resealed and sent back to the site for data entry. The unblinded site staff will re-open the envelope

to enter the data into Advantage eClinical[SM]. After data entry, the envelope will be resealed and kept in a secure locker at the site.

4.3.3 Blinding

The study will be conducted according to a partially blinded study design since the colour of the two vaccines is different. With the exception of the designated unblinded site personnel described below, all study site personnel, the PI, PATH, POLYVAC and the CROs (except the unblinded team at the CROs), will remain blinded to participants' treatment assignments until final database lock and study unblinding. Those who perform the clinical evaluations (such as but not limited to assessment of medical history, vital signs assessment, and PE), will be blinded with respect to the identity of the vaccine administered to the participants. The parents will also remain blinded to the treatment received by the child, throughout the study duration.

The randomization list for participants will be developed by an independent statistician and will be used by an unblinded team at POLYVAC to label study vaccine vials and then it will be immediately sealed. During conduct of the study, a limited number of unblinded site personnel will be responsible for preparing and administering study vaccines, performing vaccine accountability, and maintaining the security of the randomization list. The unblinded site personnel will not be involved in the safety assessment of the participants or in any other aspect of the study.

If any participant experiences an SAE possibly related to receipt of study treatment, treatment allocation to the participant may be communicated to the investigator only if that information is deemed necessary to properly treat the participant for the SAE. Written procedures for blinding, storage, and opening of study codes, in compliance with the approved protocol, will be developed to ensure the study is not unnecessarily unblinded.

4.3.4 Concomitant Medications/Treatment

Childhood vaccines as per the EPI of the Government of Vietnam [Diphtheria, Tetanus, Pertussis, Haemophilus influenzae type B and Hepatitis B vaccine (DTwPHib-HepB) and Oral Polio Vaccine (OPV)] and Pneumococcal vaccines will be allowed during the study period, but they should not be administered within 7 days before or after study vaccine administration. This is required to avoid any overlap of safety event due to study vaccine and EPI vaccines. The study participants may receive additional doses of OPV as required during special immunization rounds irrespective of the timing of study vaccine.

5. Sample Size Considerations

The sample size for the study was determined based on the regulatory requirement to submit safety data for 500 vaccine recipients receiving the new vaccine. Considering a dropout rate of 10% the study will enroll 825 infants receiving vaccines at the ratio of 2:1 (550 participants receiving the liquid formulation of ROTAVIN and 275 participants receiving the frozen formulation ROTAVIN-M1®).

Immunogenicity will be assessed in participants enrolled from Quang Ninh site. It is anticipated that at least 375 infants (250 ROTAVIN recipients and 125 ROTAVIN-M1® recipients) will provide evaluable blood samples. Considering a non-evaluability rate of approximately 15%, at least 450 participants will be enrolled at this site.

Power to show that the ratio of the GMC in the liquid formation is ROTAVIN group to that in the ROTAVIN-M1® group is at least 0.5 was calculated using a one-sided two-sample t-test with a significance level of 0.025. With 250 evaluable participants in the liquid formulation group and 125 evaluable participants in ROTAVIN-M1® group and an assumed SD of the log10 IgA antibody concentrations of 0.8 which was estimated from a phase 3 clinical trial for ROTAVIND-M1 conducted in Vietnam, we will have 93% power to demonstrate the non-inferiority of ROTAVIN liquid formation to ROTAVIN-M1® in terms of GMC using a one-sided two-sample t-test with a non-inferiority margin of 0.5 and a significance level of 0.025.

With the proposed sample size of 550 participants receiving the liquid formulation of ROTAVIN, this study is designed to have 95% power to detect at least one solicited post-vaccination reaction after each vaccination if true incidence is 0.55%.

With 550 vaccinated participants in ROTAVIN liquid formulation group and 275 vaccinated participants in ROTAVIN-M1® group, the study has 90% power to detect at least a 6.8% difference in percentage of participants with solicited post-vaccination reaction between the ROTAVIN liquid formulation and ROTAVIN-M1® groups after each vaccination, assuming that the rate of the solicited reactogenicity is 5% in the ROTAVIN-M1® group and a significance level of 0.05.Interim Analyses and DSMB Safety Reviews

There are no planned interim analyses or DSMB safety reviews. The SRC will meet monthly to review the blinded data to discuss any safety concerns.

6. General Statistical Considerations

7.1 Analysis Populations

Definitions of analysis populations used are:

Enrolled Population: The enrolled population is defined as all screened participants who provide informed consent and are eligible for study participation, regardless of the participant's randomization and treatment status in the study.

Full Analysis (FA) population: The full analysis population is defined as all participants in the enrolled population who were randomized, received the first dose of the study vaccination, and provided at least one evaluable serum sample. The analysis based on this population will serve as supportive results for all immunogenicity objectives.

Participants in the FA population will be analyzed "as randomized", i.e. according to the vaccine a participant was designated to receive, which may be different from the vaccine that the participant actually received.

Per Protocol (PP) population: The per-protocol population is defined as all participants in the FA population who correctly received both study vaccines per randomization with no major protocol deviations that are determined to potentially interfere with the immunogenicity assessment of the study vaccines. This population will serve as the primary analysis population for all immunogenicity objectives. The criteria for exclusion of participants from the PP population is described in Section 10, Table A2, of this SAP.

Safety population: The safety population is defined as all participants in the enrolled population who received at least one dose of study vaccination and had any safety data available.

Participants in the safety population will be analyzed as “treated”, i.e. according to the actual vaccine received at the first dose. All safety analyses will be performed using this population. The denominators for different safety endpoints may vary according to the number of participants with available data for the specific endpoint. For instance, the solicited adverse event endpoints will be based only on those who have the corresponding CRF data regardless of other safety follow-up data.

The immunogenicity primary and secondary endpoints will be performed on the PP and FA population. Safety primary and secondary endpoints will be performed on the safety population. All other baseline and safety analyses, unless stated otherwise, will be performed on the safety population.

7.2 Descriptive Statistics and Data Listings

For continuous parameters, descriptive statistics will include number of participants, mean, standard deviation, median, and range (minimum, maximum). For categorical parameters, the number of participants and percentage of participants will be summarized. Descriptive statistics will be presented for each vaccine group and overall.

All percentages will be presented to one decimal place. Mean and median will be presented to one decimal greater than the data. Standard deviation will be presented to two decimals greater than the data. Confidence intervals will be presented to two decimals and p-values to 4 decimals. Minimum and maximum will be presented to the number of decimals in the data.

Listings will be sorted by treatment, site, participant ID and any other relevant parameters.

7.3 Definitions

Definitions used in this document are given below. Additional definitions are included in the relevant sections in *italics*.

1. ***Screening/Baseline Assessment:*** Corresponds to the assessment performed prior to vaccination on Day 1.
2. ***Post-Baseline Visit*****:** Any visit occurring on or after administration of study vaccine on Day 1. Day 1 may be considered as post-baseline visit for those assessments performed after administration of study vaccine and as baseline visit for those assessments performed before administration of study vaccine.
3. ***Duplicate Post-Baseline Visits:*** If an assessment is performed at multiple times on a given day, the most recent assessment performed on the day will be considered.

   If an assessment is performed at the scheduled post-baseline visit as well as unscheduled visits, then the results of the scheduled visit will be used in the tabular summaries and figures.

   In the absence of assessments recorded on the scheduled visit, the following convention must be used for reporting:

   - Day 1: If post-baseline assessments were not performed on Day 1, then these assessments will be considered missing in the corresponding tabular summaries and figures.

- Post-Baseline Visit Other Than Day 1: If an assessment is only performed at unscheduled visits, then the results of the assessment performed closest to the target date of the visit will be used in the tabular summaries and figures.

Assessments performed at all visits will be listed.

4. Calculation of Time Variables:

a. Days relative to a reference date (e.g., Day 1)

For events occurring on or after the reference date:

Time in Days = Date of event – Reference date + 1

For events occurring before the reference date:

Time in Days = Date of event – Reference date

b. Duration of events or medications

Duration = End date of event or medication – Start date of event or medication + 1

c. Time in Months

Time in Months = Time in Days/30.4

d. Time in Years

Time in Years = Time in Days/365.25

7.4 Missing Data

In general, all missing data will be treated as missing completely at random and no imputation will be performed.

7.5 Multiple Comparisons/Multiplicity

ROTAVIN and ROTAVIN-M1® will be primarily compared based on a single primary immunogenicity endpoint and a single safety endpoint, respectively. No multiplicity adjustment will be carried out for primary endpoints according to the intersection-union property[1]. Using the intersection-union test method, the null hypothesis is expressed as the union of the two primary endpoints, the alternative hypothesis is expressed as the intersection. The null hypothesis is rejected if both endpoints are rejected. The overall type I error rate is not inflated therefore a multiplicity adjustment is not required.

7.6 Software for Analyses

Statistical analyses will be performed using SAS version 9.4 or higher. All tables, listings and figures presented in the analysis will be created using either SAS v9.4 or higher.

7. Participant Disposition and Screen Failures

8.1 Participant Disposition

Participant disposition including the number of participants screened, screen failed and enrolled, and the number and percentage of participants enrolled but not vaccinated, vaccinated at dose

1, 2 and both doses, safety population, FA population, and PP population, visit completion, completed the study, terminated early from the study, and discontinued the vaccine will be summarized by vaccine group and overall (Table 1). Reason for early termination from the study and from the vaccine will also be summarized.

Participant flow as outlined in Figure 1 will also be presented.

Participants who terminated early from the study will be listed (Listing 1).

8.2 Screen Failures

Participants who screen failed will be summarized (Table 2).

8. Demographics and Baseline Characteristics

9.1 Demographics

Participant demographic and baseline characteristics will be tabulated descriptively by vaccine group and overall (Table 3a-Table 3c) and listed (Listing 2). Demographic variables to be summarized include age, ethnicity, gender, and weight. Table 3a and Table 3b will be calculated for the safety population and the FA population, respectively. If more than 10% of the FA population is excluded from the PP population, the description and comparability of the vaccine groups at baseline will be repeated on the PP population (Table 3c). Group comparison will be performed to confirm whether the vaccine groups are similar with regard to demographic and baseline characteristics, using 2-sample t-test for the continuous parameters or Fisher's exact test for the categorical parameters with a significance level of 0.05.

9.2 Medical History

This will include history of participation in a drug research/clinical trial, immunization history, any ongoing diarrhea or other illness. It will also include past medical history, vaccination history, surgical history, previous hospitalizations, history of any allergy to drugs or vaccines, current medication history. and any significant family history, including history of immunodeficiency in any household member. All events will be coded using Medical Dictionary for Regulatory Activities (MedDRA).

The number and percentage of participants experiencing medical history events will be summarized by MedDRA system organ class and preferred term (Table 4). Results will be tabulated for the safety population by vaccine group and overall. Medical history reported by each participant will be listed with any concurrent illnesses separately identified (Listing 3). *Concurrent illnesses are defined as those medical history events that (a) occurred prior to Day 1 and was ongoing as of Day 1 or (b) occurred on or after Day 1*.

Other medical and family history will be summarized (Table 5) and listed (Listing 4).

9. Protocol Compliance

Any departures from protocol-specified procedures, trial documents or any other information relating to the conduct of the trial will be documented and reported as protocol deviations.

Protocol deviations and protocol violations will also be summarized by deviation/violation category for the safety population by vaccine group and overall (Table 6 and 7, respectively). Protocol deviations will be listed (Listing 5). Non-participant specific protocol deviations will also be listed (Listing 6).

Participants excluded from the analysis population, either from the safety, FA, or PP population, will be summarized by vaccine group and overall (Table 8) and listed (Listing 7).

Table A2: Analysis Population Inclusion/Exclusion

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
1.	Did not meet I-E criteria but randomized	Participant did not meet inclusion criterion	Participant did not meet inclusion criterion 1: Healthy infant as established by medical history and clinical examination before entering the study.	No PD review	Exclude
2.	Did not meet I-E criteria but randomized	Participant did not meet inclusion criterion	Participant did not meet inclusion criterion 2: Age: 60-91 days (both days inclusive) at the time of enrollment	No PD review	Exclude
3.	Did not meet I-E criteria but randomized	Participant did not meet inclusion criterion	Participant did not meet inclusion criterion 3: Parental/LAR ability and willingness to provide written informed consent.	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
4.	Did not meet I-E criteria but randomized	Participant did not meet inclusion criterion	Participant did not meet inclusion criterion 4: Parent/LAR who intends to remain in the area with the child during the study period	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
5.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 1: Presence of diarrhea or vomiting in the previous 72 hours or on the day of enrolment (temporary exclusion).	No PD review	Exclude
6.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 2: Presence of fever on the day of enrolment (temporary exclusion).	No PD review	Include
7.	Did not meet I-E criteria	Participant met exclusion criterion	Participant met exclusion criterion	No PD review	Include

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
	but randomized		3: Acute disease at the time of enrolment (temporary exclusion).		
8.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 4: Concurrent participation in another clinical trial at any point throughout the entire timeframe of this study.	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
9.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 5: Presence of severe malnutrition (weight-for-height z-score < -3SD median).	No PD review	Exclude
10.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 6: Any systemic disorder cardiovascular, pulmonary, hepatic, renal, gastrointestinal, hematological, endocrine, immunological, dermatological, neurological, cancer or autoimmune disease) as determined by medical history and/or physical examination which would compromise the child's health or is likely to result in non-conformance to the protocol.	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
11.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 7: History of congenital abdominal disorders, intussusception, abdominal surgery	No PD review	Include
12.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 8: Known or suspected impairment of immunological function based on medical history and physical examination.	No PD review	Exclude
13.	Did not meet I-E criteria	Participant met exclusion criterion	Participant met exclusion criterion	No PD review	Include

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
	but randomized		9: Household contact with an immunosuppressed individual or pregnant woman.		
14.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 10: Prior receipt of rotavirus or an intent to receive this vaccine from outside of the study center during study participation.	No PD review	Exclude
15.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 11: Prior receipt of EPI vaccination during past 7 days or plan to receive them within next 7 days.	No PD review	Include
16.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 12: A known sensitivity or allergy to any components of the study vaccine.	No PD review	Include
17.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 13: History of allergy to antibiotic kanamycin.	No PD review	Include
18.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 14: Clinically detectable significant congenital or genetic defect.	No PD review	Include
19.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 15:History of persistent diarrhea (defined as diarrhea that lasts 14 days or longer).	No PD review	Exclude
20.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 16: Receipt of immunoglobulin therapy and / or blood products since birth or planned administration during the study period.	No PD review	Exclude
21.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 16: History of chronic administration (defined as more than 14 days) of immunosuppressants including corticosteroids. Infants on inhaled or topical steroids may	No PD review	Exclude

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
			be permitted to participate in the study.		
22.	Did not meet I-E criteria but randomized	Participant met exclusion criterion	Participant met exclusion criterion 18: Any medical condition in the parents/LAR or infant that, in the judgment of the investigator, would interfere with or serves as a contraindication to protocol adherence	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
23.	Randomized to wrong treatment arm	Dosed with wrong treatment arm at visit 1	Received vaccine which is not as per randomization schedule generated for the study	No PD review	Exclude
24.	Wrong IP administered	Wrong vaccine of other arm administered at Dose 2	Due to wrong IP allocation, the participant received vaccine which is not as per randomization schedule generated for the study	No PD review	Exclude
25.	Wrong IP administered	Damaged / Expired / Quarantined IP used without prior approval	Participant received expired / damaged / quarantined vaccine	No PD review	Exclude
26.	Received Prohibited Medication /Vaccinations / Therapies	Receipt of blood products/ immunoglobulins outside the study center	Receipt of Prohibited Medication / immunoglobulin therapy and / or blood products during the study period.	No PD review	Exclude
27.	Received Prohibited Medication /Vaccinations / Therapies	Received Licensed Rotavirus vaccine during the study	Administration of any protocol prohibited vaccine including Licensed Rotavirus vaccine (outside of the study centre) during the study period.	No PD review	Exclude
28.	Missed Visit Procedure	Post vaccination assessment missed	Study Procedure related to Medical History / Physical Examination / Vital signs / AE / SAE / 30 mins observation post vaccination is not performed.	No PD review	Include
29.	Missed Visit Procedure	Post-vaccination blood sample missed to be collected from	Post-vaccination blood Sample collection is not performed for immunogenicity	No PD review	Exclude

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
		eligible participant			
30.	Missed Visit Procedure	Assessments (e.g. PE, vitals) at scheduled Visits	Study Procedure related to Medical History / Physical Examination / Vital signs / AE / SAE were not performed at scheduled visits.	No PD review	Include
31.	Deviation to allowable window period	Post vaccination assessment done beyond protocol specified timeline	Study Procedure related to Medical History / Physical Examination / Vital signs / AE / SAE / 30 min observation post vaccination is not performed within specified window period	No PD review	Include
32.	Deviation to allowable window period	Study Procedure Not Performed as per Protocol Visit Schedule	First Dose of vaccine is not administered orally between 60-91 days of life of infant.	No PD review	Exclude
33.	Deviation to allowable window period	Blood sample collected outside specified window period	Blood Sample Collection done after 4 (+2) weeks after last dose of study vaccination	No PD review	Exclude
34.	Deviation to allowable window period	Dose 1 administration beyond 24 hours of randomization	Dose 1 is administration after 24 hours of randomization	No PD review	Include
35.	Deviation to allowable window period	Out of Window Dose 2 Vaccine Administration	Second Dose of vaccine is not administered as per window period (8 +2 weeks from Dose 1)	No PD review	Exclude
36.	Study vaccine administration	Any of the study vaccine dose not administered	Any of the study vaccine dose not administered	No PD review	Exclude
37.	Temperature excursion	Temperature excursion: transit/ storage (IP)	Vaccine has been administered despite a storage temperature deviation not approved by the sponsor or vaccine has been administered from a batch where the temperature was not monitored.	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
38.	Inappropriate Blood Collection / Processing	Blood sample not processed correctly as per requirement	Blood sample for immunogenicity not processed correctly as per requirement	PD review	Decision will be taken on the case by case basis during the review of final protocol deviation listing performed prior to database lock
39.	Study vaccine administration	Incorrect route of vaccine administration	Incorrect route of vaccine administration	No PD review	Exclude
40.	Study drug administration	Vaccine has been administered out of the expiration date at the time of administration without sponsor's approval.	Vaccine has been administered out of the expiration date at the time of administration without sponsor's approval.	No PD review	Exclude
41.	Informed Consent Not Taken	--	Informed Consent is Not Taken at screening visit	No PD review	Exclude
42.	Incorrect/Unapproved ICF version used	--	Incorrect/Unapproved ICF version is used at screening visit	No PD review	Include
43.	Incorrect Informed consent process followed	Impartial Witness not used	Impartial Witness is not used at screening visit	No PD review	Include
44.	Dosed when withdrawal / discontinuation criteria met.	Dosed when withdrawal / discontinuation criteria met. (except discontinuation reason - Prohibited Medication)	Participant is discontinued from the study with any reason except discontinuation reason - Prohibited Medication	No PD review	Include
45.	SAE not reported within timelines	Initial SAE reporting not done within the timelines	Initial SAE reporting is not done within the timelines	No PD review	Include

N	Protocol Deviation Category	Protocol Deviation Subcategory	Detailed Exclusion Description	PD Assessment	Decision for Per Protocol Population
46.	Immunogenicity result not available	Serological results unavailability	Serological results not available for any of the sampling timepoint (including lost samples, blood sample not done, unable to test, absence of parallelism).	No data review. This exclusion will be filtered at "Analysis Level"	Exclude
47.	Study vaccine administration	Vomiting after repeat dose administration	Subjects who had vomiting/ regurgitation within 5 minutes of repeat dose vaccine administration	No data review. This exclusion will be filtered at "Analysis Level"	Exclude

10. Prior and Concomitant Medications

All medications taken since birth are recorded. *Prior medications are defined as those medications taken prior to Day 1 and not continued to be taken on or after Day 1; concomitant medications are defined as those medications continued to be taken or newly initiated on or after Day 1*. All medications will be coded using World Health Organization (WHO) Drug Dictionary.

Prior will be summarized by the anatomical-therapeutic component (ATC) levels 1 and 3 (Table 9). Concomitant medications will be summarized by ATC levels 1 and 3 after any dose and after each dose (Table 10-12). Results will be tabulated for the safety population by the vaccine group and overall. All medications will be listed with concomitant medications separately identified (Listing 8).

Concomitant vaccinations will be summarized by vaccination. Results will be tabulated for the safety population for each vaccine group and overall (Table 13). All EPI vaccinations will be listed (Listing 9).

11. Primary Analyses

12.1 Immunogenicity

GMC along with the two-sided 95% CI is calculated by exponentiation of the anti-log of the arithmetic mean of the $\log_{10}$-transformed concentrations. GMC along with the two-sided 95% CI for IgA at baseline and 28 days after the second vaccination will be summarized descriptively by vaccine group for the PP and FA population (Tables 14 and 15, respectively).

Non-inferiority in the immunogenicity of ROTAVIN in comparison to ROTAVIN-M1® is defined as the ratio of GMCs between ROTAVIN and ROTAVIN-M1® is larger than 1/2. The following hypothesis will be tested:

H_0: $GMC_{ROTAVIN}/GMC_{ROTAVIN\text{-}M1} \leq ½$

H1: $GMC_{ROTAVIN}/GMC_{ROTAVIN\text{-}M1} > ½$

The ratio of GMCs between ROTAVIN and ROTAVIN-M1® along with the two-sided 95% CI is calculated using the log10-transformed anti-rotavirus IgA concentrations to construct a two-sided 95% CI for the mean difference between the two study vaccines using the t-distribution. The mean difference and corresponding 95% CI are exponentiated to obtain the GMC ratio and the corresponding 95% CI. If the lower limit of the 95% CI of the ratio of GMCs between ROTAVIN and ROTAVIN-M1® is larger than 1/2, ROTAVIN is considered to be non-inferior to ROTAVIN-M1®. This results in a one-sided type I error rate of 0.025.

The ratio of the GMCs 28 days after the second dose will be provided along with the two-sided 95% CI for the PP and FA population (Tables 14 and 15, respectively).

The non-inferiority test on the 95% CI for the ratio of GMCs on the PP population is considered the primary analysis. The remaining immunogenicity analyses are considered supportive.

If the serum anti-rotavirus IgA antibody concentration is below the lowered limit of quantitation (LLOQ), i.e. assay is recorded as "<LLOQ", then the concentration will be set to half that limit (LLOQ/2). If the concentration is above the upper limit of quantitation (ULOQ), an actual value will be reported.

An analysis of covariance (ANCOVA) model with the $\log_{10}$-transformed concentrations as the dependent variable, the vaccine group as the explanatory variable, and the $\log_{10}$-transformed baseline concentrations as a covariate will also be performed for the PP and FA population (Tables 14 and 15, respectively). This adjusted analysis will be considered as supportive.

ANCOVA Model: $\log_{10}$-transformed concentrations = $\beta_0 + \beta_1$Vaccine Group + $\beta_2 \log_{10}$-transformed baseline concentrations

Immunology data will be listed (Listing 10).

12.2 Safety

The number and percentage of participants experiencing solicited post-vaccination reactogenicity (fever, diarrhea, vomiting, decreased appetite, irritability, decreased activity level) during the 7-day period after any dose will be tabulated by vaccine group and severity (Table 16). For the percentage within each group, an exact two-sided 95% CI will be provided using Clopper-Pearson method. The percentage of participants with at least one solicited post-vaccination reactogenicity between ROTAVIN and ROTAVIN-M1® groups after both doses and after each vaccination will be compared using a two-sided Fisher's Exact test with a significance level of 0.05. Results will be tabulated for the safety population for participants with available data. These results will be repeated after each dose (Tables 17 and 18) and are considered as supportive.

Solicited reactions will be presented by severity for each vaccine group after any vaccinations and after each vaccination (Figure 2-4).

Solicited reactions will be listed (Listing 11). Separate listings will be presented for solicited reactions ongoing on day 7 (Listing 12) and severe solicited reactions (Listing 13).

12. Secondary Analyses

13.1 Immunogenicity

For participants with a negative pre-vaccination IgA concentration (< 20 IU/ml), a participant is considered as seroconverted if the participant has a positive post-vaccination IgA concentration (≥ 20 IU/ml). For participants with a positive pre-vaccination IgA concentration, a participant is considered as seroconverted if the participant has a post-vaccination IgA concentration at least 4 times as high as the pre-vaccination IgA concentration.

Seropositivity is defined as serum IgA antibody concentration ≥ 20 IU/ml.

The number and percentage of participants with seroconversion in IgA antibodies 28 days after the second vaccination, will be summarized for each vaccine group for the PP and FA population (Tables 19 and 20, respectively). The exact 95% CI using the Clopper-Pearson method for the percentage of participants will be computed for each vaccine group. The difference in the percentage between the two groups (ROTAVIN and ROTAVIN-M1®) will be provided along with its two-sided 95% CI using the Miettinen and Nurminen method. The same analyses will be repeated for seropositivity for the PP and FA population (Table 21 and Table 2022 respectively).

A reverse cumulative distribution (RCD) curve for anti-rotavirus IgA concentrations will be created by vaccine group and visit for the PP and FA population (Figure 5 and 6, respectively). RCD curves are considered as supportive.

Geometric mean concentration and 95% CIs will be plotted by vaccine group for the PP and FA population (Figure 7 and 8, respectively).

13.2 Safety

13.2.1 Immediate Adverse Events

Number and percentage of participants, and total number of events, with immediate adverse events within 30 minutes after any dose and after each dose will be tabulated for each vaccine group and overall by preferred term and severity (Tables 23-25) and by preferred term and relationship with study vaccine (Table 26-27). Results will be tabulated for the safety population. For the percentage, an exact two-sided 95% CI will be provided using Clopper-Pearson method.

Immediate adverse events will be listed (Listing 14).

13.2.2 Unsolicited Adverse Events (AEs)

Solicited reactions that occur within 7 days after any study vaccination are recorded in the PIDC Reconciliation: Reactogenicity Form. Solicited reactions that become SAEs, i.e. participant was hospitalized, need to be recorded in the Serious Adverse Event Report Form. To trigger the Serious Adverse Event Report Form, the Adverse Event Form must be filled out first, which results in the solicited reactions, that become a SAE within 7 days after any study vaccination, recorded twice as a solicited reaction and an unsolicited reaction. To avoid double counting these events, they will be summarized in tables relating to solicited reactions and SAEs but not in unsolicited adverse event tables. All other reported AEs that start after vaccination and are within four weeks after each vaccination will be tabulated. If a given disease is already reported as ongoing at the first visit on the medical history pages, it will be counted and tabulated as a

vaccine emergent adverse event only if it worsens after the immunization with the study vaccine. When an adverse event occurs more than once for a participant, the maximal severity and strongest relationship to the vaccine group will be counted.

The number and percentage of participants, and total number of events, with unsolicited adverse events within four weeks will be tabulated after any dose and after each dose for each vaccine group and overall by system organ class, preferred term, and severity (Table 29-21) and by system organ class, preferred term, and relationship with study vaccine (Table 32-34). Results will be tabulated for the safety population. For the percentage, an exact two-sided 95% CI will be provided using Clopper-Pearson method.

The number and percentage of participants experiencing unsolicited AEs will be summarized after any dose and after each dose by MedDRA system organ class and preferred term (Table 35-37). This summary will be repeated for related unsolicited AEs, unsolicited AEs leading to withdrawal from the study, and unsolicited AEs leading to withdrawal from study vaccination but follow-up continued (Tables 38-42). Results will be tabulated for the safety population for each vaccine group and overall.

Unsolicited AEs by MedDRA system organ class will be presented by relationship to study vaccine (Figure 9) and severity (Figure 10) for each vaccine group.

All unsolicited AEs will be listed (Listing 15). All related unsolicited AEs will be listed (Listing 16).

13.2.3 Serious Adverse Events (SAEs)

The number and percentage of participants, and total number of events, with SAEs including intussusception reported through 4 weeks after the last vaccination will be tabulated after any dose and after each dose for each vaccine group and overall by system organ class, preferred term, and severity (Table 43-45) and by system organ class, preferred term, and relationship to study vaccine (Table 46-48). Results will be tabulated for the safety population. For the percentage, and exact two-sided 95% CI will be provided using Clopper-Pearson method.

The number and percentage of participants experiencing SAEs including intussusception reported through 4 weeks after the last vaccination will be summarized after any dose and after each dose by MedDRA system organ class and preferred term (Table 49-51). This summary will be repeated for related SAE, and unsolicited AEs leading to hospitalization and deaths (Tables 52-56). Results will be tabulated for the safety population for each vaccine group and overall.

All SAEs will be listed (Listing 17).

13.2.4 Deaths

All deaths will be tabulated by system organ class and preferred term (Table 56) and listed (Listing 18).

13. Other Safety Analyses

An overall safety summary of AEs (Table 57) will be included. This table will be based on the safety population for each vaccine group and overall.

14.1 Vaccination

The study vaccine (ROTAVIN or ROTAVIN-M1) is administered twice during the study on Day 1 and Day 57. Vaccination information will be summarized by vaccine group and overall (Table 58) and will be listed (Listing 19). Participants randomized but not vaccinated are summarized in Table 1.

14.2 Solicited Reactions

In addition to the primary analyses, solicited adverse events will be tabulated by onset day and duration in days after any dose and after each dose by vaccine group and overall (Table 59-61). These analyses are based on total number of events. Results will be tabulated for the safety population for participants with available data.

The number and percentage of participants experiencing an ongoing event at Day 7 will be tabulated after any dose and after each dose by vaccine group and overall (Table 62-64). These analyses will be tabulated for the safety population for participants with available data.

14.3 Vital Signs

Vital signs including heart rate, axillary temperature, and respiratory rate, are assessed at all visits. Further, vital signs are assessed 30 minutes after each vaccination.

For each visit, vital sign parameters will be summarized using mean, standard deviation (SD), median, and range (minimum, maximum). Change from baseline will also be presented. The number and percentage of participants with normal, abnormal and not clinically significant and abnormal and clinically significant vital signs will also be included (Tables 65-67). Results will be tabulated by vaccine group and overall for the safety population for participants with data at the given visit.

The number and percentage of participants with normal assessment pre-dose and abnormal CS/NCS assessment 30 Min post-dose will be summarized will be tabulated by vaccine group and overall for the safety population for participants with available data Table 68-70.

Boxplots will be used to show vital sign measurements over time graphically (Figure 11 through Figure 13).

Vital sign measurements and assessments made at each visit and 30 minutes post each vaccination will also be listed. (Listing 20).

14.4 Physical Examination

General appearance, head & neck, eyes, ears, nose & throat, lymph nodes, skin and subcutaneous tissue, respiratory, cardiovascular, gastrointestinal, genitourinary, central nervous system, and musculoskeletal and connective tissue, and other systems are assessed as part of physical examination at all visits. Further, targeted physical examination may be assessed 30 minutes after each vaccination, if indicated.

For each visit, the number and percentage of participants with normal, abnormal and not clinically significant, and abnormal and clinically significant body systems will be summarized (Table 71).

Summaries will be presented for each vaccine group and overall. Results will be tabulated for the safety population for participants with data at the given visit.

Physical examinations made at each visit and post each vaccination will also be listed (Listing 21).

14. References

1. Berger, R.L. and Hsu, J.C. 1996, “Bioequivalence trials, intersection-union tests, and equivalence confidence sets.” *Statistical Science*, 11, 283-319.

15. Tables, Listings and Figures

16.1 Tables

Table 1: Participant Disposition

	ROTAVIN	ROTAVIN-M1	Total
Screened[a]			x
Screen Failure[a]			x
Enrolled[a]			x
Randomized	x (x)	x (x)	x (x)
Randomized but not Vaccinated	x (x)	x (x)	x (x)
Received Dose 1	x (x)	x (x)	x (x)
Received Dose 2	x (x)	x (x)	x (x)
Received all Doses	x (x)	x (x)	x (x)
Safety Population	x (x)	x (x)	x (x)
Full Analysis (FA) Population	x (x)	x (x)	x (x)
Per Protocol (PP) Population	x (x)	x (x)	x (x)
Number of Participants who Completed			
Visit 1	x (x)	x (x)	x (x)
Visit 2	x (x)	x (x)	x (x)
Visit 3	x (x)	x (x)	x (x)
Completed Study	x (x)	x (x)	x (x)
Early Terminated from Study	x (x)	x (x)	x (x)
Parent withdrew consent	x (x)	x (x)	x (x)
Investigator discretion	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)
Discontinued the Vaccine	x (x)	x (x)	x (x)
Parent withdrew consent	x (x)	x (x)	x (x)
Investigator discretion	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)

	ROTAVIN	ROTAVIN-M1	Total
x (%) is presented, unless otherwise specified. [a]Number of participants is presented. Percentages are based on the total number of randomized participants in the enrolled population in each vaccine group and overall.			

Table 2: Screen Failures

	Total N=xx	
	x	**%**
Number of Screen Failures	**x**	**x.x**
Number Who Did Not Meet Eligibility Criteria	**x**	**x.x**
Inclusion Criteria Not Met	**x**	**x.x**
Healthy infants as established by medical history and clinical examination before entering the study.	x	x.x
Age: 60-91 days (both days inclusive) at the time of enrollment.	x	x.x
Parental/LAR ability and willingness to provide written informed consent.	x	x.x
Parent/LAR who intends to remain in the area with the child during the study period.	x	x.x
Exclusion Criteria Met	**x**	**x.x**
Presence of diarrhea or vomiting in the previous 72 hours or on the day of enrollment (temporary exclusion).	x	x.x
Presence of fever on the day of enrollment (temporary exclusion)	x	x.x
Acute disease at the time of enrollment (temporary exclusion)	x	x.x
Concurrent participation in another clinical trial at any point throughout the entire timeframe for this study.	x	x.x
Presence of significant malnutrition (weight-for-height z-score < -3SD median)	x	x.x
Presence of any systemic disorder (cardiovascular, pulmonary, hepatic, renal, gastrointestinal, hematological, endocrine, immunological, dermatological, neurological, cancer, or autoimmune disease) as determined by medical history and / or physical examination which would compromise the participant's health or is likely to result in nonconformance to the protocol.	x	x.x
History of congenital abdominal disorders, intussusception, or abdominal surgery.	x	x.x
Known or suspected impairment of immunological function based on medical history and physical examination.	x	x.x
Household contact with an immunosuppressed individual or pregnant woman.	x	x.x
Prior receipt of rotavirus or an intent to receive this vaccine from outside of the study center during study participation.	x	x.x
Prior receipt of EPI vaccination during past 7 days or plan to receive them within next 7 days.	x	x.x

A known sensitivity or allergy to any components of the study vaccine.	x	x.x
History of allergy to antibiotic kanamycin.	x	x.x
Clinically detectable significant congenital or genetic defect.	x	x.x
History of persistent diarrhea (defined as diarrhea that lasts 14 days or longer).	x	x.x
Receipt of immunoglobulin therapy and / or blood products since birth or planned administration during the study period.	x	x.x
History of chronic administration (defined as more than 14 days) of immunosuppressants including corticosteroids. Infants on inhaled or topical steroids may be permitted to participate in the study.	x	x.x
Any medical condition in the parent/LAR or infant which, in the judgment of the Investigator, would interfere with or serves as a contraindication to protocol adherence.	x	x.x
Other	**x**	**x.x**

N=Total number of participants who screen failed

x=Number of participants who screened failed

A participant who is a screen failure may not have satisfied multiple eligibility criteria; therefore, the sum of participants in the individual inclusion/exclusion criteria rows may not add up to the total number of participants who did not meet eligibility criteria.

Table 3a: Demographic and Baseline Characteristics – Safety Population

	ROTAVIN N=XX	ROTAVIN-M1 N=XX	Total N=XX	p-value[a]
Age (Days)				
n	x	x	x	0.xxxx
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	
Median	x	x	x	
Range (Min, Max)	x, x	x, x	x, x	
Ethnicity, N (%)				
Vietnamese	x (x)	x (x)	x (x)	0.xxxx
Chinese	x (x)	x (x)	x (x)	
Other	x (x)	x (x)	x (x)	
Gender, N (%)				
Male	x (x)	x (x)	x (x)	0.xxxx
Female	x (x)	x (x)	x (x)	
Birth Weight (kg)				
n	x	x	x	0.xxxx
Mean (SD)	x.xx (x.xxx)	x.xx (x.xxx)	x.xx (x.xxx)	
Median	x.x	x.x	x.x	
Range (Min, Max)	x.x, x.x	x.x, x.x	x.x, x.x	

N=Total number of participants in the FA population in each vaccine group and overall.
n=Number of participants with non-missing values
Percentages are based on the total number of participants in the FA population in each vaccine group and overall.
[a] p-value based on the t-test or Fisher's exact test comparing ROTAVIN and ROTAVIN-M1®

Programming note: If there are missing values for any of the categorial parameters, then a separate row corresponding to "Missing" must be added under than category.

Table 3b: Demographic and Baseline Characteristics – FA Population

{This table will be similar to Table 3a}

Table 3c: Demographic and Baseline Characteristics – PP Population

{This table will be similar to Table 3a}

Programming note: If more than 10% of the FA population is excluded from the PP population, the description and comparability of the vaccine groups at baseline will be repeated on the PP population.

Table 4: Medical history by System Organ Class and Preferred Term – Safety Population

MedDRA System Organ Class Preferred Term	ROTAVIN N=XX x (%)	ROTAVIN-M1 N=XX x (%)	Total N=XX x (%)
Participants with at least one Medical History Event	**x (x)**	**x (x)**	**x (x)**
SOC1	**x (x)**	**x (x)**	**x (x)**
PT1	x (x)	x (x)	x (x)
PT2	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)
SOC2	**x (x)**	**x (x)**	**x (x)**
PT1	x (x)	x (x)	x (x)
PT2	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)

N=Total number of participants in the safety population

x=Number of participants with a medical history event

Percentages are based on the total number of participants in the safety population.

A participant may be counted in multiple rows within each system organ class; however, they will be counted only once in the overall row for the system organ class. Therefore, the sum of participants within each system organ class may not add up to the overall row for the system organ class.

All medical history terms coded and reviewed on MedDRA version XX.X.

Table 5: Other Medical History – Safety Population

	ROTAVIN N=XX x (%)	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**
Drug/vaccine allergy	**x (x)**	**x (x)**	**x (x)**
Yes	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)
Participation in interventional drug research study or other vaccine clinical trial	**x (x)**	**x (x)**	**x (x)**
Yes	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)
History on immunodeficiency in any house hold member	**x (x)**	**x (x)**	**x (x)**
Yes	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)
Pregnancy in any family member living in the same household	**x (x)**	**x (x)**	**x (x)**
Yes	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)
N=Total number of participants in the safety population x=Number of participants with an event Percentages are based on the total number of participants in the safety population.			

Table 6: Protocol Deviations by Category – Safety Population

Protocol Deviation Category	ROTAVIN N=XX x (%), E	ROTAVIN-M1 N=XX x (%), E	Total N=XX x (%), E
Total	**x (%) , E**	**x (%), E**	**x (%), E**
Incomplete vaccination: Subject declined further vaccination but safety follow up continued	x (%), E	x (%), E	x (%), E
Incorrect Informed consent process	x (%), E	x (%), E	x (%), E
Incorrect Procedure	x (%), E	x (%), E	x (%), E
Missed Procedures	x (%), E	x (%), E	x (%), E
Subject confidentiality compromised: Personal data of subject transmitted to unintended recipient/s	x (%), E	x (%), E	x (%), E
Temperature excursion	x (%), E	x (%), E	x (%), E
Visit Window Deviation: Post vaccination assessment done before protocol specified timeline	x (%), E	x (%), E	x (%), E
Other	x (%), E	x (%), E	x (%), E

N=Total number of participants in the safety population

E=Total number of protocol deviations

x=Number of participants with a protocol deviation

Percentages are based on the total number of participants in the safety population.

If multiple protocol deviations are reported for a participant, the participant may be counted in multiple rows corresponding to the different protocol deviation categories; however, they will be counted only once in the “Total” row. Therefore, the sum of participants may not add up to the “Total” row.

Programming Note: Print only the categories that have data

Table 7: Protocol Violations by Category – Safety Population

Protocol Violations Category	ROTAVIN N=XX x (%), E	ROTAVIN-M1 N=XX x (%), E	Total N=XX x (%), E
Total	**x (%), E**	**x (%), E**	**x (%), E**
Did not meet I / E criteria but enrolled	x (%), E	x (%), E	x (%), E
Dosed when withdrawal / discontinuation criteria were met	x (%), E	x (%), E	x (%), E
Incomplete vaccination: Replacement dose not administered in case of vomiting within 5 mins of administration	x (%), E	x (%), E	x (%), E
Informed Consent Not Taken	x (%), E	x (%), E	x (%), E
Incorrect Informed consent process: LAR not used when required	x (%), E	x (%), E	x (%), E
Damaged / Expired IP / Quarantined kit used without prior approval	x (%), E	x (%), E	x (%), E
Missed Procedures	x (%), E	x (%), E	x (%), E
Randomized to wrong treatment arm: Dosed with wrong treatment arm at visit 1	x (%), E	x (%), E	x (%), E
Wrong treatment arm administered at second dose	x (%), E	x (%), E	x (%), E
Receipt of Prohibited Medications / vaccinations / Therapies	x (%), E	x (%), E	x (%), E
Safety reporting beyond regulatory timelines	x (%), E	x (%), E	x (%), E

Visit Window Deviation	x (%), E	x (%), E	x (%), E
Other	x (%), E	x (%), E	x (%), E

N=Total number of participants in the safety population

E=Total number of protocol violations

x=Number of participants with a protocol violation

Percentages are based on the total number of participants in the safety population as defined in the protocol.

If multiple protocol violations are reported for a participant, the participant may be counted in multiple rows corresponding to the different protocol violations categories; however, they will be counted only once in the “Total” row. Therefore, the sum of participants may not add up to the “Total” row.

Programming Note: Print only the categories that have data

Table 8: Analysis Populations

Analysis Population	Reason Participants Excluded	ROTAVIN	ROTAVIN-M1	Total
Safety Population	Number of participants	x (100.0%)	x (100.0%)	x (100.0%)
	Any Reason for Exclusion	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 1]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 2]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	…			
Full Analysis Population	Number of participants	x (100.0%)	x (100.0%)	x (100.0%)
	Any Reason for Exclusion	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 1]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 2]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	…			
Per Protocol Population	Number of participants	x (100.0%)	x (100.0%)	x (100.0%)
	Any Reason for Exclusion	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 1]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	[Reason 2]	x (xx.xx%)	x (xx.xx%)	x (xx.xx%)
	…			

Table 9: Prior Medications – Safety Population

WHO Drug Dictionary ATC Level 1/ Level 3	**ROTAVIN N=XX x (%)**	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**
Any prior medication	**x (x)**	**x (x)**	**x (x)**
ATC Level 1 - 1	**x (x)**	**x (x)**	**x (x)**
ATC Level 3 - 1	x (x)	x (x)	x (x)
ATC Level 3 - 2	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)
ATC Level 1 - 2	**x (x)**	**x (x)**	**x (x)**
ATC Level 3 - 1	x (x)	x (x)	x (x)
ATC Level 3 - 2	x (x)	x (x)	x (x)
…	x (x)	x (x)	x (x)

N=Total number of participants in the safety population in each vaccine group and overall.
x=Number of participants with a prior medication

Percentages are based on the total number of participants in the safety population in each vaccine group and overall.

A participant may be counted in multiple rows within each ATC Level 1 classification; however, they will be counted only once in the overall row for the ATC Level 1 classification. Therefore, the sum of participants within each ATC Level 1 classification may not add up to the overall row for the ATC Level 1 classification.

All medications coded and reviewed on WHO Drug version XX.

Programming note: Medications may be sorted by descending frequency of ATC Level 1 and/or Level 3 classifications.

Table 10: Concomitant Medications – Safety Population – After Any Dose

{This table will be similar to Table 9}

Table 11: Concomitant Medications – Safety Population – After Dose 1

{This table will be similar to Table 9}

Table 12: Concomitant Medications – Safety Population – After Dose 2

{This table will be similar to Table 9}

Table 13: Concomitant Vaccinations – Safety Population

	ROTAVIN N=XX x (%)	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**
Any Concomitant Vaccination	**x (x)**	**x (x)**	**x (x)**
BCG vaccine	x (x)	x (x)	x (x)
Hepatitis b vaccine	x (x)	x (x)	x (x)
Polio vaccine live oral	x (x)	x (x)	x (x)
Diphtheria vaccine toxoid; Hepatitis b vaccine; HIB vaccine; Pertussis vaccine; Tetanus vaccine toxoid	x (x)	x (x)	x (x)
Pneumococcal vaccines	x (x)	x (x)	x (x)
Other	x (x)	x (x)	x (x)

N=Total number of participants in the safety population in each vaccine group and overall.
x=Number of participants with a concomitant vaccination

Percentages are based on the total number of participants in the safety population in each vaccine group and overall

For participants with at multiple Concomitant vaccinations, the participant may be counted in multiple rows corresponding to different vaccinations; however, they will be counted only once in the “Any Concomitant Vaccination” row. Therefore, the sum of participants may not add up to the “Any Concomitant Vaccination” row.

Table 14: Geometric Mean Concentration (GMC) for IgA – PP Population

Day		ROTAVIN	ROTAVIN-M1	GMC Ratio (95% CI[b])	Adjusted GMC Ratio (95% CI)[c]
Day 1	Number of observations	xx	xx		
	Mean (SD) Log10 Concentration	xx.xx (xx.xxx)	xx.xx (xx.xxx)		
	GMC	xx	xx		
	95% CI[a] of GMC	(xx, xx)	(xx, xx)		
	Range (Min, Max) of Concentration	(xx, xx)	(xx, xx)		
Day 85	Number of observations	xx	xx		
	Mean (SD) Log10 Concentration	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	GMC	xx	xx		
	95% CI[a] of GMC	(xx, xx)	(xx, xx)		
	Range (Min, Max) of Concentration	(xx, xx)	(xx, xx)		
…					
…					

[a]CI = Confidence interval from the log-normal distribution

[b]CI = Confidence interval based on the t-distribution on the mean difference of the $\log_{10}$-transformed concentrations between vaccination groups.

[c]Adjusted GMC Ratio based on ANCOVA model: $\log_{10}$ concentration at Day 85 = $\beta_0 + \beta_1$Vaccine Group + $\beta_2 \log_{10}$ concentration at Day 1

Table 15: Geometric Mean Concentration (GMC) for IgA – FA Population

{This table will be similar to Table 14}

Table 16: Solicited Reactions – Safety Population –After Any Dose

	ROTAVIN N=XX		**ROTAVIN-M1 N=XX**		**Total N=XX**		**p-value[a]**
Solicited Reaction	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	
Number of participants, n	**x**		**x**		**x**		
Participants with at least one Solicited Reaction	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**0.xxxx**
Any							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Fever							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Diarrhea							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	

	ROTAVIN N=XX		ROTAVIN-M1 N=XX		Total N=XX		p-value[a]
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x) , x	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Vomiting							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Decreased appetite							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Irritability							
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Decreased activity level							

	ROTAVIN N=XX		ROTAVIN-M1 N=XX		Total N=XX		p-value[a]
Total	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Mild	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Moderate	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	
Severe	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	

N= Total number of participants in the safety population in each vaccine group and overall.
n=Number of participants with non-missing values
x=Number of participants with a solicited reaction
E=Total number of solicited reactions

Percentages are based on the total number of participants in the safety population with non-missing values for at least one solicited adverse event in each vaccine group.

CI= Exact Confidence Interval using Clopper-Pearson

[a]p-value is based on the Fisher exact test comparing ROTAVIN and ROTAVIN-M1

Table 17: Solicited Reactions – Safety Population – After Dose 1

{This table will be similar to Table 16}

Programming Note: E terminology will not be included in this table

Table 18: Solicited Reactions – Safety Population – After Dose 2

{This table will be similar to Table 16}

Programming Note: E terminology will not be included in this table

Table 19: Seroconversion for IgA at Day 85 – PP Population

	ROTAVIN	ROTAVIN-M1	Percentage Difference (95% CI[b])
Number of observations	xx	xx	
x (%)	xx (xx.x)	xx (xx.x)	xx.x (xx.xx, xx.xx)
95% CI[a]	(xx.xx, xx.xx)	(xx.xx, xx.xx)	

N=Total number of participants in the PP population in each vaccine group

x=Number of participants who seroconverted

Percentages are based on the total number of participants in the PP population in each vaccine group.

[a]CI= Exact Confidence Interval using Clopper-Pearson

[b]CI of the difference in the percentage between the two vaccine groups from the Miettinen and Nurminen method

Table 20: Seroconversion for IgA at Day 85 – FA Population

{This table will be similar to Table 19}

Table 21: Seropositivity for IgA – PP Population

Day		ROTAVIN	ROTAVIN-M1	Percentage Difference (95% CI[b])
Day 1	Number of observations	xx	xx	
	x (%)	xx (xx.x)	xx (xx.x)	xx.x (xx.xx, xx.xx)
	95% CI[a]	(xx.xx, xx.xx)	(xx.xx, xx.xx)	
Day 85	Number of observations	xx	xx	
	x (%)	xx (xx.x)	xx (xx.x)	xx.x (xx.xx, xx.xx)
	95% CI[a]	(xx.xx, xx.xx)	(xx.xx, xx.xx)	

N=Total number of participants in the PP population in each vaccine group

x=Number of participants with seropositivity

Percentages are based on the total number of participants in the PP population in each vaccine group.

[a]CI= Exact Confidence Interval using Clopper-Pearson

[b]CI of the difference in the percentage between the two vaccine groups from the Miettinen and Nurminen method

Table 22: Seropositivity for IgA – FA Population

{This table will be similar to Table 21}

Table 23: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Any Dose

	ROTAVIN N=XX										**ROTAVIN-M1 N=XX**									
	Mild		**Moderate**		**Severe**		**Life threatening**		**Death**		**Mild**		**Moderate**		**Severe**		**Life threatening**		**Death**	
MedDRA System Organ Class Preferred Term	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**
Participants with at least one Immediate AE	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
SOC 1	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
PT2	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)

N=Total number of participants in the safety population

x=Number of participants with an immediate adverse event

E=Total number of immediate adverse events

Percentages are based on the total number of participants in the safety population.

A participant is only counted once per preferred term and is summarized according to their maximum severity.

All AE terms coded and reviewed on MedDRA version XX.X.

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 24: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 1

{This table will be similar to Table 23}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 25: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 2

{This table will be similar to Table 23}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 26: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Any Dose

	ROTAVIN N=XX				ROTAVIN-M1 N=XX			
	Related		Not Related		Related		Not Related	
MedDRA System Organ Class Preferred Term	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**
Participants with at least one Immediate AE	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
SOC 1	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
PT2	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)

N=Total number of participants in the safety population

x=Number of participants with an immediate adverse event

E=Total number of immediate adverse events

Percentages are based on the total number of participants in the safety population.

A participant is only counted once per preferred term and is summarized according to their closest relationship.

All AE terms coded and reviewed on MedDRA version XX.X.

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 27: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Dose 1

{This table will be similar to Table 26}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 28: Immediate (Within 30 Minutes of Vaccination) Adverse Events by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Dose 2

{This table will be similar to Table 26}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 29: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Any Dose

	ROTAVIN N=XX										**ROTAVIN-M1 N=XX**									
	Mild		**Moderate**		**Severe**		**Life threatening**		**Death**		**Mild**		**Moderate**		**Severe**		**Life threatening**		**Death**	
MedDRA System Organ Class **Preferred Term**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**
Participants with at least one Unsolicited AE	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), x**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
SOC 1	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
PT2	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
…	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
SOC 2	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
…																				
N=Total number of participants in the safety population																				

x=Number of participants with an unsolicited AE

E=Total number of unsolicited AEs

Percentages are based on the total number of participants in the safety population.

A participant may be counted in multiple rows within each system organ class; however, they will be counted only once in the overall row for the system organ class. Therefore, the sum of participants within each system organ class may not add up to the overall row for the system organ class.

A participant is only counted once per preferred term and is summarized according to their maximum severity.

All AE terms coded and reviewed on MedDRA version XX.X.

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 30: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 1

{This table will be similar to Table 29}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 31: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 2

{This table will be similar to Table 29}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 32: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Relation with study vaccine – Safety Population – After Any Dose

	ROTAVIN N=XX N (%)				ROTAVIN-M1 N=XX N (%)			
	Related		Not related		Related		Not related	
MedDRA System Organ Class Preferred Term	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**	**x (%), E**	**95% CI**
Participants with at least one Unsolicited AE	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
SOC 1	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
PT2	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
…	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
SOC 2	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**	**x (x), E**	**(xx.xx, xx.xx)**
PT1	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)	x (x), E	(xx.xx, xx.xx)
…								

N=Total number of participants in the safety population

x=Number of participants with an unsolicited AE

E=Total number of unsolicited AEs

Percentages are based on the total number of participants in the safety population.

A participant may be counted in multiple rows within each system organ class; however, they will be counted only once in the overall row for the system organ class. Therefore, the sum of participants within each system organ class may not add up to the overall row for the system organ class.

A participant is only counted once per preferred term and is summarized according to their closest relationship.

All AE terms coded and reviewed on MedDRA version XX.X.

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 33: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Relation with study vaccine – Safety Population – After Dose 1

{This table will be similar to Table 32}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 34: Unsolicited AEs within 4 weeks after each vaccination by System Organ Class, Preferred Term, Vaccine Group, and Relation with study vaccine – Safety Population – After Dose 2

{This table will be similar to Table 32}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 35: Unsolicited AEs within four weeks after each vaccination by System Organ Class and Preferred Term – Safety Population – After Any Dose

MedDRA System Organ Class Preferred Term	ROTAVIN N=XX x (%), E	ROTAVIN-M1 N=XX x (%), E	Total N=XX x (%), E
Participants with at least one Unsolicited AE	**x (x), E**	**x (x), E**	**x (x), E**
SOC1	**x (x), E**	**x (x), E**	**x (x), E**
PT1	x (x), E	x (x), E	x (x), E
PT2	x (x), E	x (x), E	x (x), E
…	x (x), E	x (x), E	x (x), E
SOC2	**x (x), E**	**x (x), E**	**x (x), E**
PT1	x (x), E	x (x), E	x (x), E
PT2	x (x), E	x (x), E	x (x), E
…	x (x), E	x (x), E	x (x), E

N=Total number of participants in the safety population

x=Number of participants with unsolicited AEs

E=Total number of unsolicited AEs

Percentages are based on the total number of participants in the safety population.

A participant may be counted in multiple rows within each system organ class; however, they will be counted only once in the overall row for the system organ class. Therefore, the sum of participants within each system organ class may not add up to the overall row for the system organ class.

All AE terms coded and reviewed on MedDRA version XX.X.

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 36: Unsolicited AEs within four weeks after each vaccination by System Organ Class and Preferred Term – Safety Population – After Dose 1

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 37: Unsolicited AEs within four weeks after each vaccination by System Organ Class and Preferred Term – Safety Population – After Dose 2

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 38: Related Unsolicited AEs by System Organ Class and Preferred Term – Safety Population – After Any Dose

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 39: Related Unsolicited AEs by System Organ Class and Preferred Term – Safety Population – After Dose 1

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 40: Related Unsolicited AEs by System Organ Class and Preferred Term – Safety Population – After Dose 2

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 41: Unsolicited AEs Leading to Withdrawal from the Study by System Organ Class and Preferred Term – Safety Population

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 42: Unsolicited AEs Leading to Withdrawal from the Study Vaccination but Follow-up Continued by System Organ Class and Preferred Term – Safety Population

{This table will be similar to Table 35}

Table 43: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Any Dose

{This table will be similar to Table 29}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 44: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 1

{This table will be similar to Table 29}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 45: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Severity – Safety Population – After Dose 2

{This table will be similar to Table 29}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 46: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Any Dose

{This table will be similar to Table 32}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 47: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Dose 1

{This table will be similar to Table 32}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 48: SAEs by System Organ Class, Preferred Term, Vaccine Group, and Relationship with study vaccine – Safety Population – After Dose 2

{This table will be similar to Table 32}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 49: SAEs by System Organ Class and Preferred Term – Safety Population – After Any Dose

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 50: SAEs by System Organ Class and Preferred Term – Safety Population – After Dose 1

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 51: SAEs by System Organ Class and Preferred Term – Safety Population – After Dose 2

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 52: Related SAEs by System Organ Class and Preferred Term – Safety Population – After Any Dose

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 53: Related SAEs by System Organ Class and Preferred Term – Safety Population – After Dose 1

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.
E terminology will not be included in this table

Table 54: Related SAEs by System Organ Class and Preferred Term – Safety Population – After Dose 2

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

E terminology will not be included in this table

Table 55: Unsolicited AEs Leading to Hospitalization by System Organ Class and Preferred Term – Safety Population

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 56: Deaths by System Organ Class and Preferred Term – Safety Population

{This table will be similar to Table 35}

Programming Note: The SOCs will be ordered starting with the most common SOC.

Table 57: Overall Safety Summary: Adverse Events – Safety Population

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
	No. of Participants[a]	No. of Events[b]	No. of Participants[a]	No. of Events[b]	No. of Participants[a]	No. of Events[b]
Total Number of Participants Enrolled	**xx**	**xx**	**xx**	**xx**	**xx**	**xx**
Total Number of Participants receiving Dose 1	**xx**	**xx**	**xx**	**xx**	**xx**	**xx**
Total Number of Participants receiving Dose 2	**xx**	**xx**	**xx**	**xx**	**xx**	**xx**
Total Number of Vaccinations	**xx**	**xx**	**xx**	**xx**	**xx**	**xx**
Total Number of Participants in the Safety Population	**xx**	**xx**	**xx**	**xx**	**xx**	**xx**
Total Number of Events[c]	**x (x)**	**xx**	**x (x)**	**xx**	**x (x)**	**xx**
Total Immediate Adverse Events – After Any Dose	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Immediate Adverse Events – After Dose 1	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Immediate Adverse Events – After Dose 2	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Solicited Reactions[d] – After Any Dose	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Solicited Reactions[d] – After Dose 1	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Solicited Reactions[d] – After Dose 2	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Unsolicited Reactions – After Any Dose	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Unsolicited Reactions – After Dose 1	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Unsolicited Reactions – After Dose 2	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total SAEs – After Any Dose	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Outcome						
Ongoing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Unknown/lost to follow up	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved without sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved with sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Stabilized	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total SAEs – After Dose 1	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Outcome						
Ongoing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Unknown/lost to follow up	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved without sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved with sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Stabilized	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total SAEs – After Dose 2	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severity						
Mild	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Life threatening	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Outcome						
Ongoing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)		ROTAVIN-M1 x (%)		Total x (%)	
Unknown/lost to follow up	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved without sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Recovered/resolved with sequelae	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Stabilized	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Death	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Deaths – After Any Dose	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Deaths – After Dose 1	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Total Deaths – After Dose 2	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**	**x (x)**
Relationship to Study Vaccine						
Related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not related	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	ROTAVIN x (%)	ROTAVIN-M1 x (%)	Total x (%)
x=Number of participants with an event [a]Percentages are based on the total number of participants in the safety population in each vaccine group and overall. [b]Percentages are based on the total number of events reported in each vaccine group and overall. [c]Solicited reactions that become SAEs or that start within 30 minutes of vaccination are only counted as one event for the number of events. [d]Percentages are based on the number of participants with available data. Participants may experience a given event multiple times during the study with differing severities and/or outcomes relation to IP; therefore, the sum of participants may not add up to the total row for the event. A participant may be counted in multiple rows for a given event if they experienced the event multiple times with differing severities or relation to IP; however, they will be counted only once in the overall row for that event. Therefore, the sum of participants may not add up to the overall row for the event.			

Table 58: Vaccination Administration – Safety Population

	Dose 1			Dose 2		
	ROTAVIN N=XX x (%)	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**	**ROTAVIN N=XX x (%)**	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**
Was vaccination given to the participant?						
Yes	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Reason vaccination was not given						
Receipt of licensed rotavirus vaccine from outside	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Reaction to an earlier dose of vaccine	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Other	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Route of administration						
Oral	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Other	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Did the participant spit or regurgitate most of the vaccine within 5 minutes of administration						
Yes	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

	Dose 1			Dose 2		
	ROTAVIN N=XX x (%)	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**	**ROTAVIN N=XX x (%)**	**ROTAVIN-M1 N=XX x (%)**	**Total N=XX x (%)**
No	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Was repeat dose administered						
Yes	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Did the participant spit or regurgitate most of the vaccine within 5 minutes of repeat dose?						
Yes	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
No	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

N=Total number of participants in the safety population

x=Number of participants with an event

Percentages are based on the total number of participants in the safety population.

Table 59: Onset and Duration (Days) of Solicited Adverse Events – Safety Population – After Any Dose

Characteristic	ROTAVIN N=XX	ROTAVIN-M1 N=XX	Total N=XX
Onset Day			
Any Solicited AE			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x
Fever			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x
Diarrhea			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x
…			
Duration (Days)			
Any Solicited AE			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x
Fever			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x
Diarrhea			
n	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x

Range (Min, Max)	x, x	x, x	x, x
…			
N=Number of those vaccinated and who have the corresponding CRF data in each vaccine group and overall. n=Number of participants with non-missing values Analyses are based on the number of events			

Table 60: Onset and Duration (Days) of Solicited Adverse Events – Safety Population – After Dose 1

{This table will be similar to Table 59}

Table 61: Onset and Duration (Days) of Solicited Adverse Events – Safety Population – After Dose 2

{This table will be similar to Table 59}

Table 62: Solicited Adverse Events Ongoing at Day 7 – Safety Population – After Any Dose

Solicited Reaction	ROTAVIN N=XX x (%)	ROTAVIN-M1 N=XX x (%)	Total N=XX x (%)
Number of participants, n	**x**	**x**	**x**
Participants with at least one Ongoing Solicited Reaction	**x (x)**	**x (x)**	**x (x)**
Any			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Fever			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Diarrhea			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Vomiting			

Solicited Reaction	ROTAVIN N=XX x (%)	ROTAVIN-M1 N=XX x (%)	Total N=XX x (%)
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Decreased appetite			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Irritability			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)
Decreased activity level			
Ongoing at Day 7	x (x)	x (x)	x (x)
Highest grade:			
None	x (x)	x (x)	x (x)
Mild	x (x)	x (x)	x (x)
Moderate	x (x)	x (x)	x (x)
Severe	x (x)	x (x)	x (x)

Solicited Reaction	ROTAVIN N=XX x (%)	ROTAVIN-M1 N=XX x (%)	Total N=XX x (%)
N= Total number of participants in the safety population in each vaccine group and overall. n=Number of participants with non-missing values x=Number of participants with an ongoing symptom beyond 7 days Percentages are based on the total number of participants in the safety population with non-missing values for at least one solicited adverse event in each vaccine group.			

Table 63: Solicited Adverse Events Ongoing at Day 7 – Safety Population – After Dose 1

{This table will be similar to Table 62}

Table 64: Solicited Adverse Events Ongoing at Day 7 – Safety Population – After Dose 2

{This table will be similar to Table 62}

Table 65: Vital Signs – Heart Rate Over Time – Safety Population

	Heart Rate (Beats/min)			Change from Baseline (Beats/min)		
	ROTAVIN	ROTAVIN-M1	Total	ROTAVIN	ROTAVIN-M1	Total
Baseline						
n	x	x	x			
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)			
Median	x.x	x.x	x.x			
Range (Min, Max)	x, x	x, x	x, x			
Normal, N (%)	x (x)	x (x)	x (x)			
Abnormal NCS, N (%)	x (x)	x (x)	x (x)			
Abnormal CS, N (%)	x (x)	x (x)	x (x)			
30 Min (After Dose 1)						
n	x	x	x	x	x	x
Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
Median	x.x	x.x	x.x	x.x	x.x	x.x
Range (Min, Max)	x, x	x, x	x, x	x, x	x, x	x, x
Normal, N (%)	x (x)	x (x)	x (x)			
Abnormal NCS, N (%)	x (x)	x (x)	x (x)			
Abnormal CS, N (%)	x (x)	x (x)	x (x)			
Day 57						
…						
…						
…						
…						
…						
30 Min (After Dose 2)						
…						
…						

	Heart Rate (Beats/min)			Change from Baseline (Beats/min)		
	ROTAVIN	**ROTAVIN-M1**	**Total**	**ROTAVIN**	**ROTAVIN-M1**	**Total**
Day 85						
…						
…						
n=Number of participants with non-missing values Percentages are based on the total number of participants in the safety population with non-missing values for heart rate at the given visit in each vaccine group and overall.						

Table 66: Vital Signs – Axillary Temperature Over Time – Safety Population

{This table will be similar to Table 65}

Table 67: Vital Signs – Respiratory Rate Over Time – Safety Population

{This table will be similar to Table 65}

Table 68: Vital Signs – Shift Table for Heart Rate– Safety Population

Dose	30 Min Post-Dose	Heart Rate (Beats/min) Normal at Pre-Dose		
		ROTAVIN	ROTAVIN-M1	Total
Dose 1				
	Abnormal CS	x (x)	x (x)	x (x)
	Abnormal NCS	x (x)	x (x)	x (x)
Dose 2				
	Abnormal CS	x (x)	x (x)	x (x)
	Abnormal NCS	x (x)	x (x)	x (x)

Percentages are based on the total number of participants in the safety population with non-missing values for heart rate at the given visit in each vaccine group and overall.

Table 69: Vital Signs – Shift Table for Axillary Temperature– Safety Population

{This table will be similar to Table 68}

Table 70: Vital Signs – Shift Table for Respiratory Rate– Safety Population

{This table will be similar to Table 68}

Table 71: Abnormal Physical Examination Over Time – Safety Population

Body System		ROTAVIN	ROTAVIN-M1	Total
General appearance	**Baseline**			
	n			
	Abnormal NCS, N (%)	x (x)	x (x)	x (x)
	Abnormal CS, N (%)	x (x)	x (x)	x (x)
	30 Min (After Dose 1)			
	n			
	Abnormal NCS, N (%)	x (x)	x (x)	x (x)
	Abnormal CS, N (%)	x (x)	x (x)	x (x)
	Day 57			
	…			
…	…			

n=Number of participants with non-missing values

Percentages are based on the total number of participants in the safety population with non-missing values for at least one physical examination assessment at the given visit in each vaccine group and overall.

16.2 Listings

Listing 1: Early Terminations

Treatment	Site	Participant ID	Reason for premature termination from the study	Did the participant complete vaccination?	Reason for vaccine discontinuation	Date of last clinic visit	Date of last contact
ROTAVIN	Nam Dinh	RN001	Parent withdrew consent (DDMMMYY)	Yes		DDMMMYY	DDMMMYY
		RN002	Adverse event (xxx)	Yes		DDMMMYY	DDMMMYY
	Quang Ninh	xxx	Death (DDMMMYY)	No	xxx	DDMMMYY	DDMMMYY
		xxx	Protocol violation (xxx)	Yes		DDMMMYY	DDMMMYY
ROTAVIN-M1	Nam Dinh	xxx	Lost to follow-up/unknown	No	xxx	DDMMMYY	DDMMMYY
		*xxx	Other (xxx)	No	xxx	DDMMMYY	DDMMMYY
*Indicates participants who were enrolled but not vaccinated, and therefore excluded from the safety population.							

Programming note: If reason for termination is “Parent withdrew consent” or “Death”, then print the date; if reason for termination is “Investigator discretion”, then print the specified reason; if reason for termination is “Adverse event”, then print the MedDRA preferred term from ***Adverse Events*** form; if reason for termination is “Protocol violation”, then print the relevant information from the ***End of Study*** form; for any other reason for termination, print the relevant information from the ***End of Study*** form.

Listing 2: Demographics and Baseline Characteristics – Safety Population

Treatment	Site	Participant ID	Age (Days)	Ethnicity	Gender	Birth Weight (kg)	
ROTAVIN	Nam Dinh	xxx	xx	xxx	Male	x.x	
		xxx	xx	xxx	Female	x.x	
	Quang Ninh	xxx	xx	xxx	xxx	x.x	
		xxx	xx	xxx	xxx	x.x	
ROTAVIN-M1	Nam Dinh	xxx	xx	xxx	xxx	x.x	
		xxx	xx	xxx	xxx	x.x	
		xxx	xx	xxx	xxx	x.x	
		xxx	xx	xxx	xxx	x.x	

Programming note: If Ethnicity is ‘Other’ then print the specify details in parenthesis.

Listing 3: Medical History – Safety Population

Treatment	Site	Participant ID	MH Code	History/ Condition[a]	Start Date	End Date	Start Day Relative to Enrollment	End Day Relative to Enrollment	Duration (Days)	Treatment
ROTAVIN	Nam Dinh	xxx	M1	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	No
		xxx	M2	*xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	No
	Quang Ninh	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	Yes
		xxx	xxx	*xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
Concurrent illnesses are indicated with an asterisk (*).										

Listing 4: Other Medical and Family History – Safety Population

Treatment	Site	Participant ID	Drug/Vaccine allergy (If Yes, Specify)	Participation in interventional drug research study or other vaccine clinical trial (If Yes, Specify)	History of Immunodeficiency in any house hold member (If Yes, Specify)	Pregnancy in any family member living in the same household
ROTAVIN	Nam Dinh	xxx	Yes (xxx)	No	Yes (xxx)	No
		xxx	No	Yes (xxx)	Yes (xxx)	No
	Quang Ninh	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx

Listing 5: Protocol Deviations and Violations

Treatment	Site	Participant ID	Deviation number	Classification	Category of D/V	Sub Category of D/V	Description of D/V	Date of Protocol D/V	Date of Identification	Risks	Action taken to correct the problem	Plan to prevent future occurrences	Decision by Medical Monitor
ROTAVIN	Nam Dinh	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	Yes (xxx)	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	No	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx

Abbreviations: D/V = Deviation/Violation; Risks = Do you consider the event “a problem involving risks to the participant or others”

Programming note: if the response to the category or sub category of deviation/violation or the response to Decision is “Other”, then print the specify details in parenthesis. If the response to risks is “Yes”, then print the reason why in parenthesis.

Listing 6: Non-Participant Specific Protocol Deviations

Site	Deviation number	Number of participants affected	Classification	Category of D/V	Sub Category of D/V	Description of D/V	Date of Protocol D/V	Date of Identification	Risks	Action taken to correct the problem	Plan to prevent future occurrences	Decision by Medical Monitor
Nam Dinh	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	Yes (xxx)	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	No	xxx	xxx	xxx
Nam Dinh	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx

Abbreviations: D/V = Deviation/Violation; Risks = Do you consider the event “a problem involving risks to the participant or others”

Programming note: if the response to the category or sub category of deviation/violation or the response to Decision is “Other”, then print the specify details in parentheses.

Listing 7: Participants Excluded from Analysis Population

Treatment	Site	Participant ID	Analyses in which Participant is Included	Analyses from which Participant is Excluded	Results Available?	Reason Participant Excluded
ROTAVIN	Nam Dinh	xxx	[e.g. Safety]	[e.g. Safety]		xxx
…						
ROTAVIN	Quang Ninh	xxx	[e.g. Safety, FA, PP]	[e.g. Safety, FA, PP]	Yes	xxx
…						

Note: Participants from Nam Dinh will be analyzed for inclusion in the safety population only since serum samples were not collect collected.

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

Listing 8: Prior and Concomitant Medications – Safety Population

Treatment	Site	Participant ID	When Medication was taken[a]	Medication	WHO Drug Dictionary ATC Level 3	WHO Drug Dictionary ATC Level 1	Indication	Start Date	End Date	Days Relative to Enrollment		Duration (Day)	Dose (Units)	Frequency	Route
										Start Date	End Date				
ROTAVIN	Nam Dinh	xxx	xxx	xxx	xxx	xxx	Medical history (M1)	DDMMMYY	DDMMMYY	xxx	xxx	xxx	2 mg	xxx	xxx
		xxx	xxx*	xxx	xxx	xxx	Adverse Event (A1)	DDMMMYY	DDMMMYY	xxx	xxx	xxx	1 tablet	xxx	xxx
		xxx	xxx*	xxx	xxx	xxx	Solicited reaction	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx

[a]Concomitant medications are indicated with an asterisk (*)

Programming note: if response to type of indication is “Medical history” or “Adverse Event”, then print the event code in parenthesis; if response to dose units, frequency, or route is “Other”, then print the specify details in parenthesis.

Listing 9: Concomitant Vaccinations – Safety Population

Treatment	Site	Participant ID	Vaccine Name	Date of Vaccination	Days from Enrollment	Route	Site
ROTAVIN	Nam Dinh	xxx	xxx	DDMMMYY	xxx	xxx	xxx
		xxx	xxx*	DDMMMYY	xxx	xxx	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx
		xxx*	xxx*	DDMMMYY	xxx	xxx	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	DDMMMYY	xxx	xxx	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx

Programming note: if response to vaccine name is “Other”, then print the details in parenthesis; if response to route is “Other”, then print the details in parenthesis; if response to site is “Other”, then print the details in parenthesis.

Listing 10: Immunogenicity Response Data

Treatment	Participant ID	Actual Study Day		Sample Collection Date		Baseline Concentration	Post-vaccination Concentration
		Baseline	Post-vaccination	Baseline	Post-vaccination		
ROTAVIN	xxx	1	87	DDMMMYY	DDMMMYY	xxxx	xxxx
Study day reference is Day 1.							

Listing 11: Solicited Reactions – Safety Population

Treatment	Site	Participant ID	Vaccination Number	Vaccination Date	Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Ongoing on Day 7	If yes, Last day of event	If yes, Highest grade
ROTAVIN	Nam Dinh	xxx	1	DDMMMYY	Fever	xxx	xxx	xxx	xxx	xxx	xxx	xxx	No		
		xxx	2	DDMMMYY	Diarrhea	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
	Quang Ninh	xxx	1	DDMMMYY	Vomiting	xxx	xxx	5 (Severe)	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
		xxx	1	DDMMMYY	xxx	xxx	xxx	xxx	xxx	Severe	xxx	xxx	xxx	DDMMMYY	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
Severity color coding: yellow = mild, orange = moderate, red = severe															

Listing 12: Solicited Reactions Ongoing on Day 7 – Safety Population

Treatment	Site	Participant ID	Vaccination Number	Vaccination Date	Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Ongoing on Day 7	If yes, Last day of event	If yes, Highest grade
ROTAVIN	Nam Dinh	xxx	1	DDMMMYY	Fever	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
		xxx	2	DDMMMYY	Diarrhea	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
	Quang Ninh	xxx	1	DDMMMYY	Vomiting	xxx	xxx	5 (Severe)	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
		xxx	1	DDMMMYY	xxx	xxx	xxx	xxx	xxx	Severe	xxx	xxx	Yes	DDMMMYY	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx

Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death

Listing 13: Severe Solicited Reactions – Safety Population

Treatment	Site	Participant ID	Vaccination Number	Vaccination Date	Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Ongoing on Day 7	If yes, Last day of event	If yes, Highest grade
ROTAVIN	Nam Dinh	xxx	1	DDMMMYY	Fever	xxx	xxx	xxx	xxx	xxx	xxx	xxx	No		
		xxx	2	DDMMMYY	Diarrhea	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Yes	DDMMMYY	xxx
	Quang Ninh	xxx	1	DDMMMYY	Vomiting	xxx	xxx	5 (Severe)	xxx	xxx	xxx	xxx	No		
		xxx	1	DDMMMYY	xxx	xxx	xxx	xxx	xxx	Severe	xxx	xxx	xxx	DDMMMYY	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	DDMMMYY	xxx	xxx	Severe	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	xxx	xxx	xxx	xxx	xxx	Severe	xxx	xxx	DDMMMYY	xxx
		xxx	xxx	DDMMMYY	xxx	Severe	xxx	xxx	xxx	xxx	xxx	xxx	xxx	DDMMMYY	xxx
Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death															

Listing 14: Immediate (Within 30 Minutes of Vaccination) Adverse Events – Safety Population

Treatment	Site	Participant ID	Adverse Event Code	Event Term	System Organ Class	Preferred Term	First sign or symptom date and time	Associated Dose (Time post Dose)	Date and Time of Resolution	Duration (Days)	Severity	SAE (SAE Number)	Relation to Study Vaccine	Action taken for further dose	Other action taken for treatment	Outcome
ROTAVIN	Nam Dinh	xxx	A1	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose xx (xx minutes)	Ongoing		Severe	Yes (CVIA 068-EN-001)	Not related	xxx	xxx	
		xxx	xxx	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose x (xx minutes)	Ongoing		Moderate	No	Related	xxx	xxx	
	Quang Ninh	xxx	xxx	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose x (xx minutes)	DDMMMY Y; hh:mm	xx	xxx	xx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose x (xx minutes)	DDMMMY Y; hh:mm	xx	xxx	xx	xxx	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose x (xx minutes)	DDMMMY Y; hh:mm	xx	xxx	xx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY ; hh:mm	Dose x (xx minutes)	DDMMMY Y; hh:mm	xx	xxx	xx	xxx	xxx	xxx	xxx

Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death

Listing 15: Unsolicited Adverse Events – Safety Population

Treatment	Site	Participant ID	Adverse Event Code	Event Term	System Organ Class	Preferred Term	First sign or symptom date and time	Associated Dose (Days/Time post Dose)[a]	Date and Time of Resolution	Duration of Event (Days)	Severity	Immediate Adverse Event	SAE (SAE Number)	Relation to Study Product	Action taken for further dose	Other action taken for treatment	Outcome
ROTAVIN	Nam Dinh	xxx	A1	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (12 days)	DDMMMY Y; hh:mm	3	Mild	No	No	Related	xxx	xxx	Recovered without sequelae
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 2 (3 days)	DDMMMY Y; hh:mm	2	Moderate	No	Yes (CVIA 068-EN-001)	Not related	xxx	xxx	Recovered without sequelae
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (25 minutes)	DDMMMY Y; hh:mm	xxx	Severe	Yes	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx*	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a]Time from vaccination is presented for immediate adverse events; otherwise days from vaccination is presented.

*Event started 4 weeks after vaccination

Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death

This listing includes solicited reactions that became SAEs within 7 days after any study vaccination.

Listing 16: Related Unsolicited Adverse Events – Safety Population

Treatment	Site	Participant ID	Adverse Event Code	Event Term	System Organ Class	Preferred Term	First sign or symptom date and time	Associated Dose (Days/Time post Dose)[a]	Date and Time of Resolution	Duration of Event (Days)	Severity	Immediate Adverse Event	SAE (SAE Number)	Action taken for further dose	Other action taken for treatment	Outcome
ROTAVIN	Nam Dinh	xxx	A1	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (12 days)	DDMMMY Y; hh:mm	3	Mild	No	No	xxx	xxx	Recovered without sequelae
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 2 (3 days)	DDMMMY Y; hh:mm	2	Moderate	No	Yes (CVIA 068-EN-001)	xxx	xxx	Recovered without sequelae
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (25 minutes)	DDMMMY Y; hh:mm	xxx	Severe	Yes	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMY Y; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a]Time from vaccination is presented for immediate adverse events; otherwise days from vaccination is presented.

Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death

This listing includes solicited reactions that became SAEs within 7 days after any study vaccination.

Listing 17: Serious Adverse Events – Safety Population

Treatment	Site	Participant ID	SAE unique identifying number	Event Term	System Organ Class	Preferred Term	Date and Time of SAE Occurrence	Associated Dose (Days post Dose)[a]	Date and Time of Resolution	Duration (Days)	Severity	Seriousness Criteria[a]	Relation to Study Product	Action taken for further dose	Outcome	Expectedness[b]
ROTAVIN	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (12 days)	DDMMMYY; hh:mm	3	Moderate	xxx	Related	xxx	Recovered without sequelae	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 2 (3 days)	DDMMMYY; hh:mm	2	Moderate	xxx	Not related	xxx	Recovered without sequelae	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	Dose 1 (25 minutes)	DDMMMYY; hh:mm	xxx	Severe	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a]Disability=Persistent or significant disability or incapacity; Hospitalization=Inpatient hospitalization or prolongation of existing hospitalization; Birth Defect=Congenital anomaly or birth defect; MIE=Medically important event.

[b]Investigator's comment for expectedness.

Severity color coding: yellow = mild, orange = moderate, red = severe, purple = life threatening, black = death

Listing 18: Deaths – Safety Population

Treatment	Site	Participant ID	SAE unique identifying number	Event Term	System Organ Class	Preferred Term	AE onset date and time	Date and Time of SAE Occurrence	Associated Dose (Days post Dose)[a]	Date and Time of Death	Relation to Study Product	Cause of death	Autopsy performed
ROTAVIN	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	Dose 1 (12 days)	DDMMMYY; hh:mm	Related	xxx	Yes
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	Dose 2 (3 days)	DDMMMYY; hh:mm	Not related	xxx	No
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	Dose 1 (25 minutes)	DDMMMYY; hh:mm	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	DDMMMYY; hh:mm	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx

Listing 19: Study Vaccination – Safety Population

Treatment	Site	Participant ID	Dose Number	Was vaccination given to the participant?	Reason vaccination was not given	Date and Time of Vaccination	Route of administration	Spit or Regurgitate	Was repeat dose administered?	Reason for not administering repeat dose	Time of repeated dose	Spit or Regurgitate after Repeat Dose?
ROTAVIN	Nam Dinh	xxx	Dose 1	Yes	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
		xxx	Dose2	Yes	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
	Quang Ninh	xxx	xxx	No	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
		xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
		xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx
		xxx	xxx	xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx	hh:mm	xxx

Abbreviations: Spit or Regurgitate = Did the participant spit or regurgitate most of the vaccine within 5 minutes of administration?
Spit or Regurgitate after Repeat Dose = Did the participant spit or regurgitate most of the vaccine within 5 minutes of repeat dose?

Programming note: if the response to “Reason vaccination was not given” or “Rout of administration” is other, then print the specify details in parentheses.

Listing 20: Vital Signs – Safety Population

Treatment	Site	Participant ID	Visit	Date and time of examination	Study Day (Days)	Heart rate (Beats/min)[a]	Axillary temperature (°C)[a]	Respiratory rate (Breaths/min)[a]
ROTAVIN	Nam Dinh	xxx	Baseline	DDMMMYY; hh:mm	xxx	xxx (CS-M1)	xxx	xxx
			30 Minutes – Post Dose 1	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			Day 57	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			30 Minutes – Post Dose 2	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			Day 85	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
	Quang Ninh	xxx	Baseline	DDMMMYY; hh:mm	xxx	xxx	xxx (NCS)	xxx
			30 Minutes – Post Dose 1	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			Day 57	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			30 Minutes – Post Dose 2	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			Day 85	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
ROTAVIN-M1	Nam Dinh	xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			…	DDMMMYY; hh:mm	…	…	…	…
		xxx	xxx	DDMMMYY; hh:mm	xxx	xxx	xxx	xxx
			…	DDMMMYY; hh:mm	…	…	…	…

Abbreviations: CS=clinically significant; NCS=not clinically significant;
[a]Abnormal findings are included in the parentheses; for CS findings, then the corresponding event code is included in parentheses.
Study day reference is Day 1.

Programming note: The listing includes all vital signs assessments, scheduled and unscheduled.

Abnormal finding should be included in parentheses; if CS finding, then include the corresponding event code in parentheses.

Listing 21: Physical Examination Findings – Safety Population

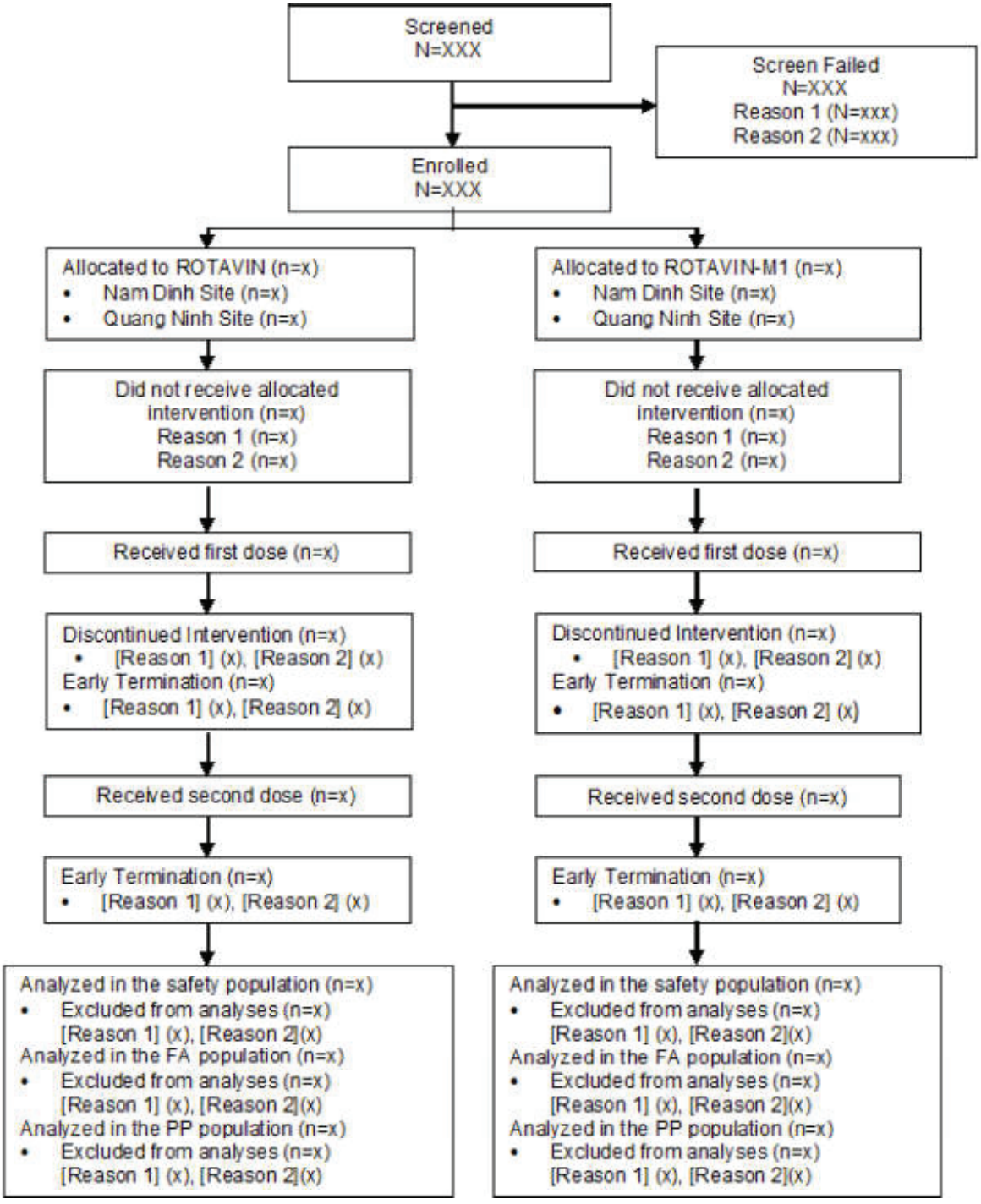
Treatment	Site	Participant ID	Visit	Current Weight (kg)	Current Length (cm)	Date and time of examination	Study Day (Days)	Body System	Assessment	Event Code
ROTAVIN	Nam Dinh	xxx	Baseline	x.x	xx	DDMMMYY; hh:mm	xxx	General appearance	Abnormal NCS	
						DDMMMYY; hh:mm	xxx	Head & neck	Abnormal NCS	
						DDMMMYY; hh:mm	xxx	Eyes	Abnormal CS	xxx
						DDMMMYY; hh:mm	xxx	Ears, nose & throat	Abnormal NCS	
						DDMMMYY; hh:mm	xxx	…	…	…
			30 Minutes – Post Dose 1			DDMMMYY; hh:mm	xxx	…	…	…
			…				xxx	…	…	…

Abbreviations: CS=clinically significant; NCS=not clinically significant
Study day reference is Day 1.

Programming note: The listing includes all physical examinations, scheduled and unscheduled. If a participant does not have any findings, they will not be included in this listing.

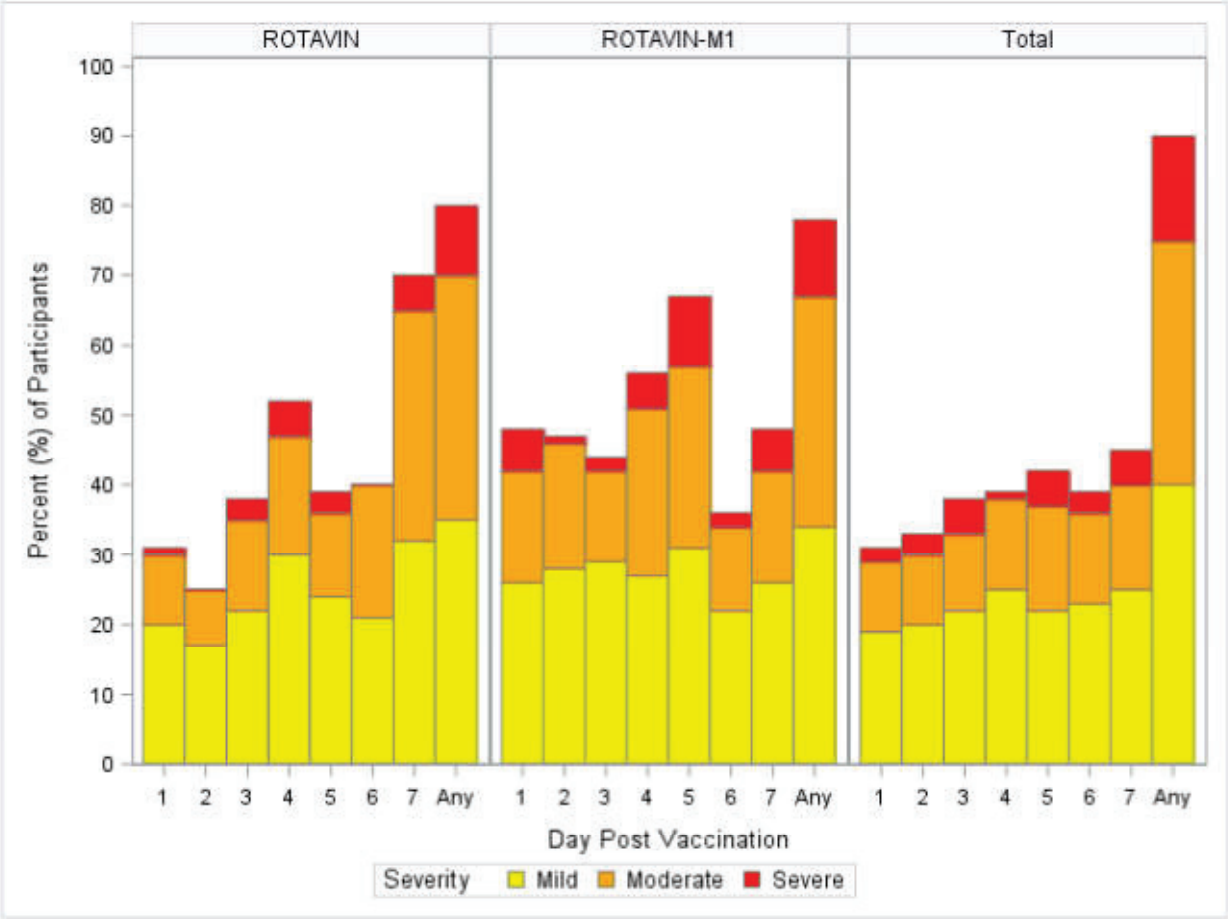
16.3 Figures

Figure 1: CONSORT Flow Diagram



Programming note: This figure will be created manually.

Figure 2: Solicited Reactions by Vaccine group and Severity – After Any Dose – Safety Population



Programming note: add data labels, number of participants, for each bar

Figure 3: Solicited Reactions by Vaccine group and Severity – After Dose 1 – Safety Population

{This figure will be similar to Figure 4}

Figure 4: Solicited Reactions by Vaccine group and Severity – After Dose 2 – Safety Population

{This figure will be similar to Figure 4}

Figure 5: Reverse Cumulative Distribution Curve of IgA Concentrations – PP Population

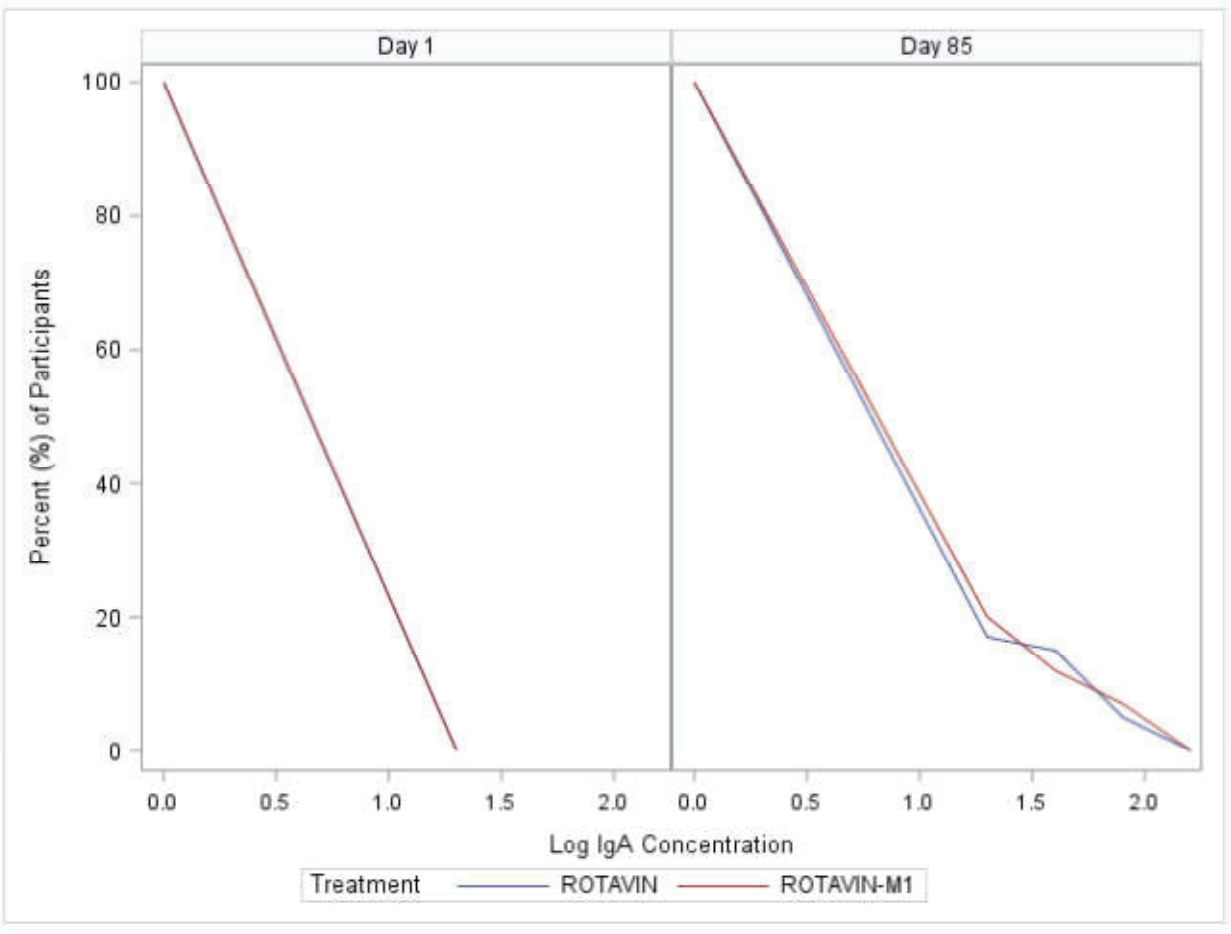


Figure 6: Reverse Cumulative Distribution Curve of IgA Concentrations – FA Population

{This figure will be similar to Figure 5}

Figure 7: Geometric Mean Concentration and 95% CI for IgA – PP Population

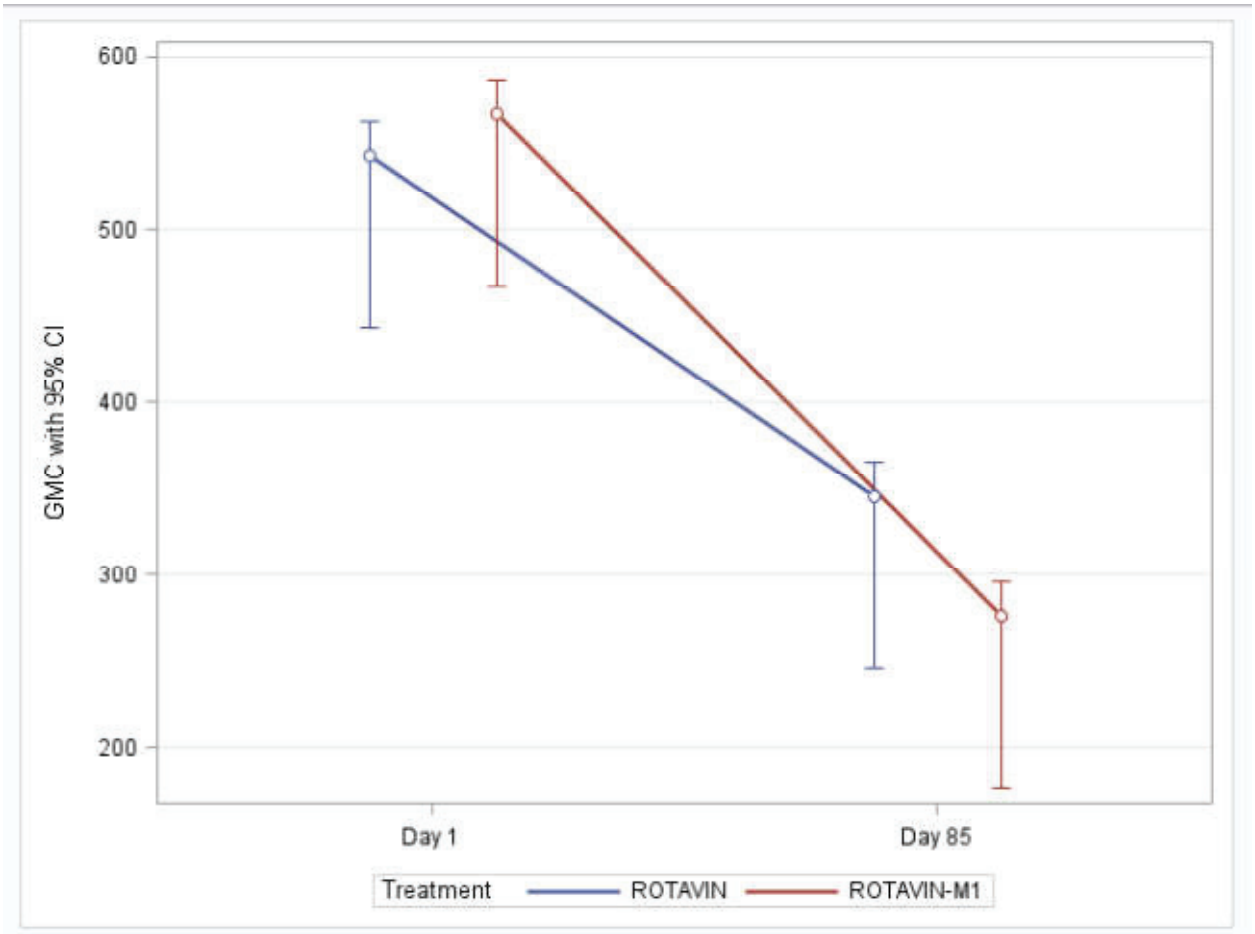
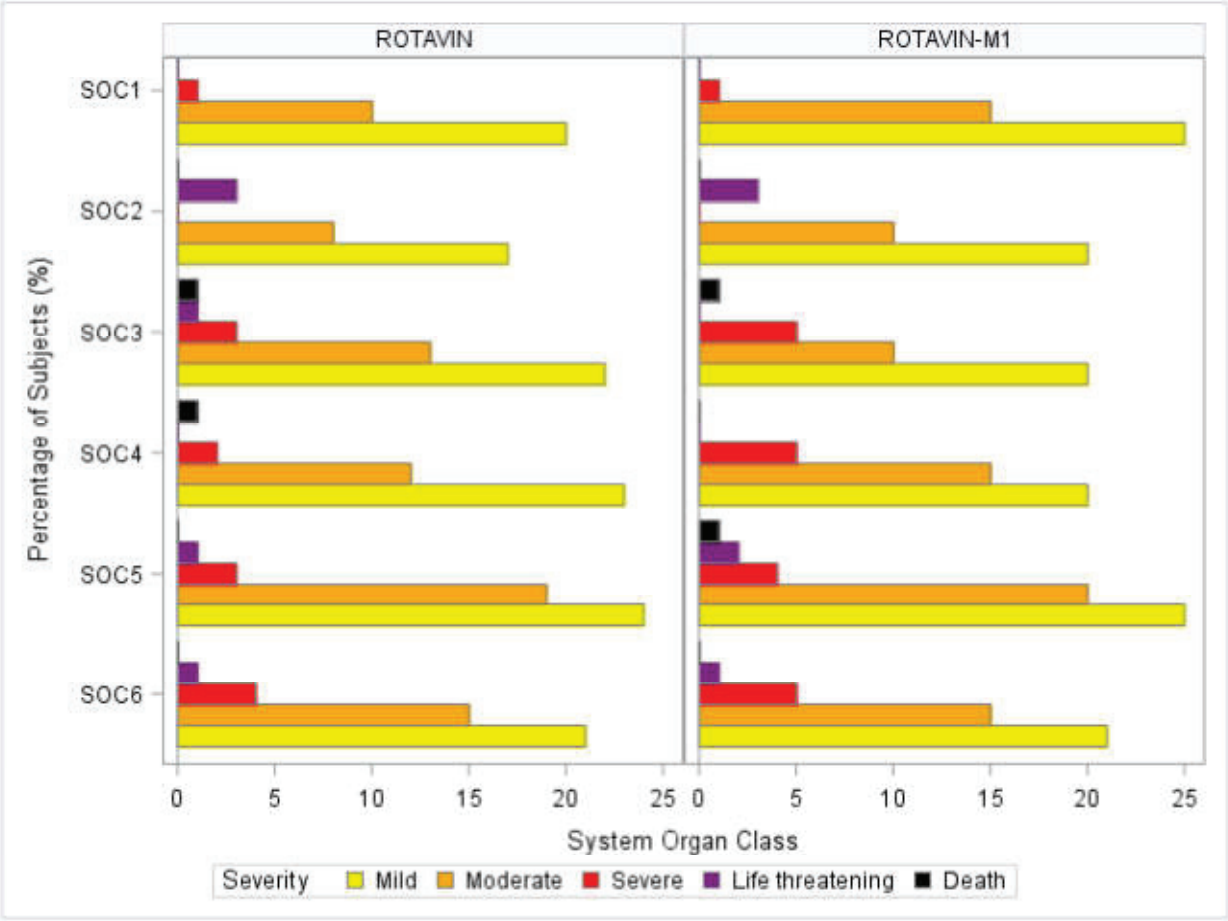


Figure 8: Geometric Mean Concentration and 95% CI for IgA – FA Population

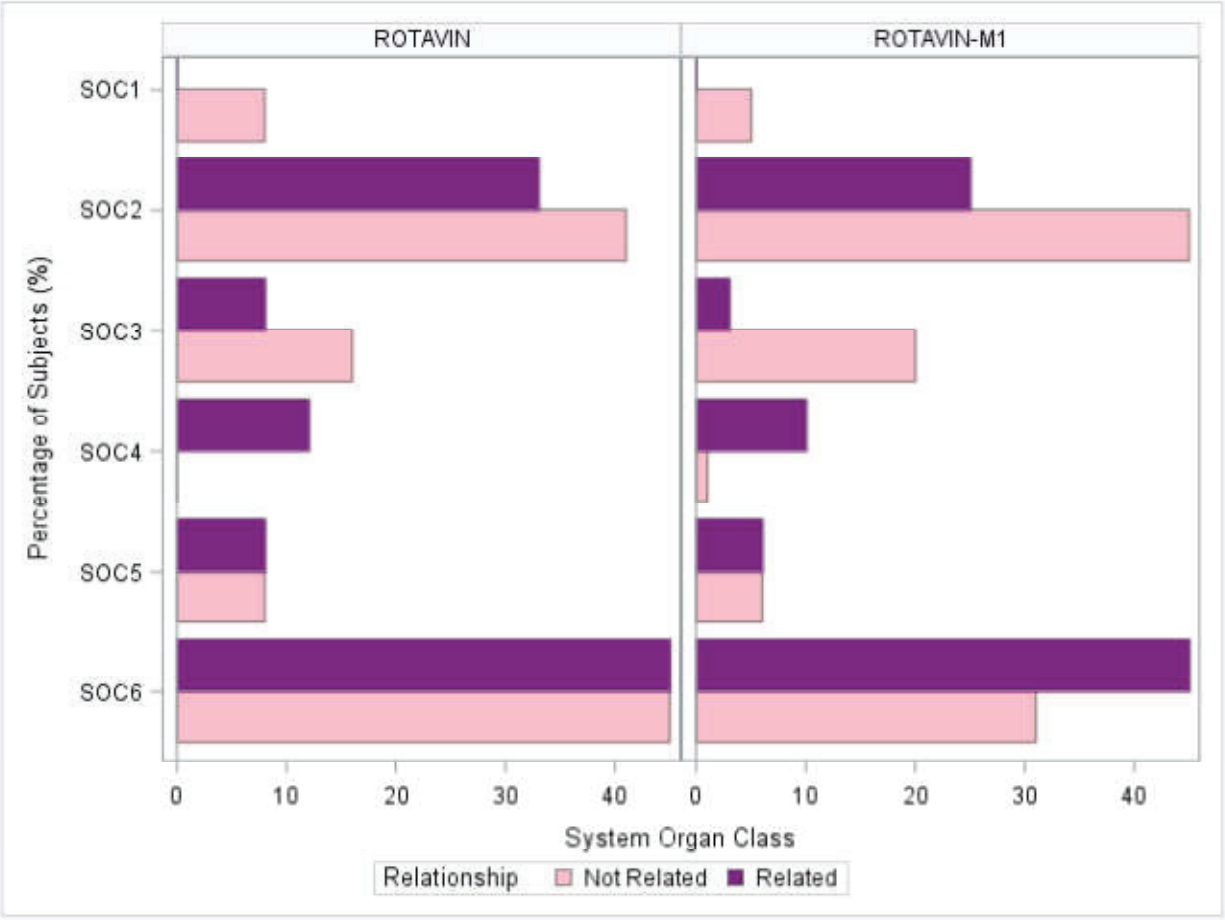
{This figure will be similar to Figure 7}

Figure 9: Unsolicited Adverse Events by MedDRA® System Organ Class and Severity – Safety Population – After Any Dose



Programming note: add data labels, number of participants, for each bar

Figure 10: Unsolicited Adverse Events by MedDRA® System Organ Class and Relationship to Study Vaccine – Safety Population – After Any Dose



Programming note: add data labels, number of participants, for each bar

Figure 11: Box Plot of Vital Signs Over Time – Heart rate – Safety Population

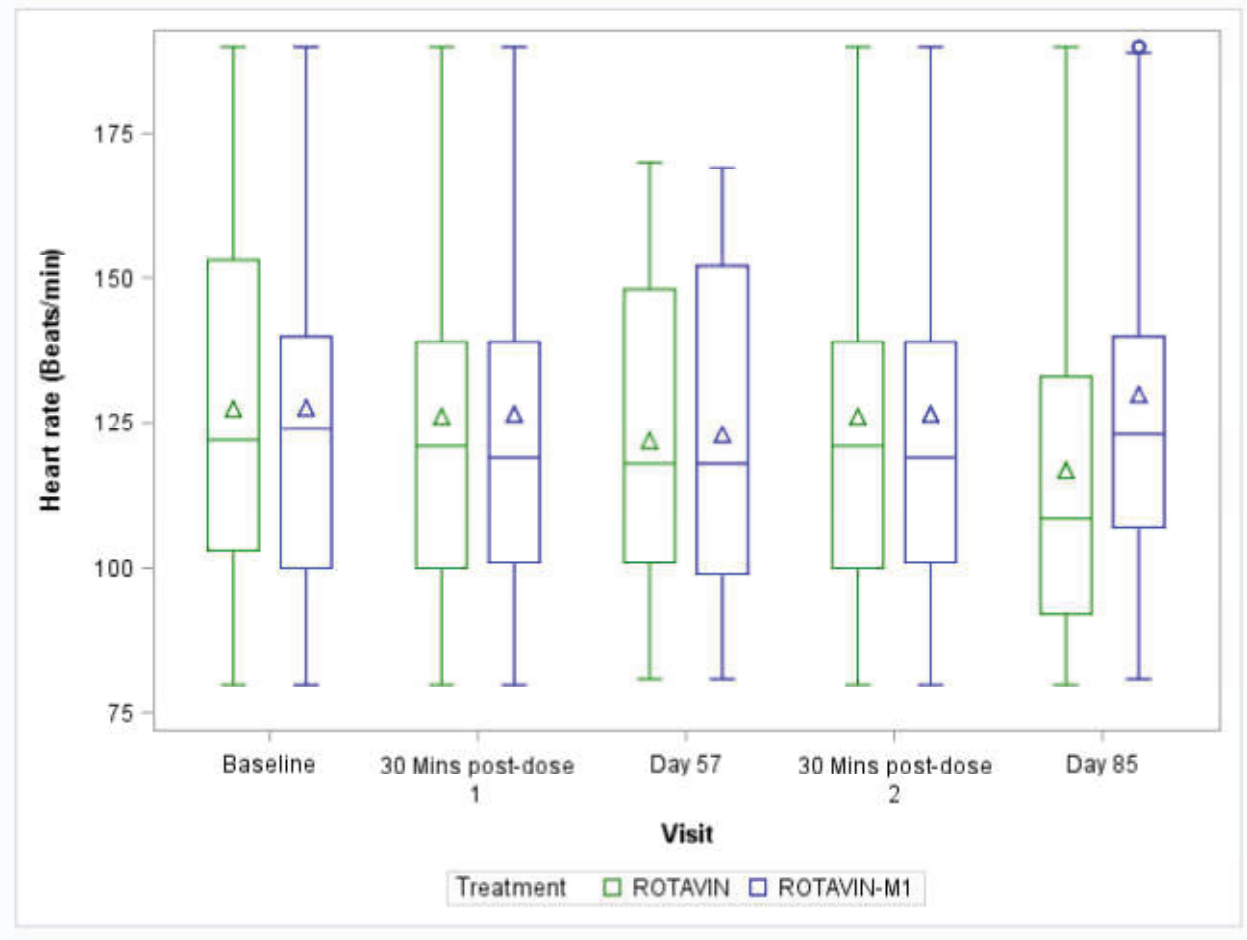


Figure 12: Box Plot of Vital Signs Over Time – Axillary temperature – Safety Population

{This figure will be similar to Figure 9}

Figure 13: Box Plot of Vital Signs Over Time – Respiratory rate – Safety Population

{This figure will be similar to Figure 9}