# STATISTICAL ANALYSIS PLAN
# for
# PATH Protocol:
# VAC 014/OEV-122 ERC/PR-14127

A Randomized, Double-blind, Placebo-controlled, Dose-Escalation Study evaluating the safety, tolerability, and immunogenicity of an oral inactivated ETEC Vaccine (ETVAX) alone and together with dmLT adjuvant in descending age groups in Bangladesh

**Version 2.0**

**08 August 2018**

Prepared and distributed by:
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Rockville, Maryland USA

# Version History

| Version / Date | Section | Description | Author |
|---|---|---|---|
| 1.0 / 04 MAY 2018 | All | This initial document was approved and signed prior to unblinding and data analysis. | L. Dally |
| 2.0 / 08 AUG 2018 | Page ii | Updated clinical trial completion date;<br>Administrative update to the confidentiality statement;<br>Updated version number and date throughout headers;<br>Added version history. | M. Carvallo |

# Study Title

| | |
|---|---|
| **Protocol Number Code:** | Protocol: PR-14127 |
| **Development Phase:** | Phase I/II |
| **Products:** | ETVAX, dMLT |
| **Form/Route:** | Vaccine/Oral |
| **Indication Studied:** | Diarrheal Disease |
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| **Clinical Trial Initiation Date:** | 13 October 2015 |
| **Clinical Trial Completion Date:** | 29 July 2017 |
| **Date of the Analysis Plan:** | 08 August 2018 |
| **Version Number:** | 2.0 |

**This study was performed in compliance with Good Clinical Practice.**

# SIGNATURE PAGE

SPONSOR: PATH

STUDY TITLE: A Randomized, Double-blind, Placebo-controlled Study evaluating the safety, tolerability, and immunogenicity of an oral inactivated ETEC Vaccine (ETVAX) alone and together with dmLT adjuvant in descending age groups in Bangladesh.

PROTOCOL: PATH Protocol: OEV-122 ERC/PR-14127

PATH Medical Officer: (Dr. Alan Fix, MD, MPH)

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# TABLE OF CONTENTS

# List of Abbreviations

| | |
|---|---|
| AE | Adverse Event |
| ALT | Alanine Aminotransferase |
| CI | Confidence interval |
| cm | Centimeter |
| CRF | Case report form |
| CSR | Clinical Study Report |
| EDC | Electronic data capture |
| ELISA | Enzyme linked immunosorbent assay |
| FA | Full Analysis |
| FDA | Food and Drug Administration |
| GMT | Geometric Mean Titer |
| HBV | Hepatitis B virus |
| HCG | Human chorionic gonadotropin |
| HCV | Hepatitis C virus |
| HgB | Hemoglobin |
| HIV | Human immunodeficiency virus |
| ICF | Informed consent form |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| Ig | Immunoglobulin |
| IM | Intramuscular |
| MedDRA | Medical Dictionary for Regulatory Activities |
| N | Number (typically refers to participants) |
| PI | Principal Investigator |
| PP | Per Protocol |
| PS | Polysaccharide |
| PT | Preferred Term |
| SAE | Serious adverse event |
| SAP | Statistical Analysis Plan |
| SD | Standard deviation |
| SOC | System Organ Class |
| ULN | Upper limit of normal |
| USA | United States of America |
| WBC | White blood cells |
| WHO | World Health Organization |

# 1 PREFACE

The Statistical Analysis Plan (SAP) for "Safety, Tolerability and Immunogenicity of a new *Enterotoxigenic Escherichia coli* Vaccine (ETVAX) containing 4 different inactivated *E. coli* strains and a hybrid LCTB*A* protein, given alone and together with different doses of dmLT adjuvant in descending age-groups" describes and expands upon the statistical information presented in the PATH protocol OEV-122/VAC-014.

This document describes all planned analyses and provides reasons and justifications for these analyses. It also includes sample tables, listings, and figures planned for the final analyses. Regarding the final analyses and Clinical Study Report (CSR), this SAP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, as indicated in Topic E3 (Structure and Content of Clinical Study Reports), and more generally is consistent with Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials). The structure and content of the SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA) and ICH, while all work planned and reported for this SAP will follow internationally accepted guidelines published by the American Statistical Association and the Royal Statistical Society for statistical practice.

This document contains four sections: (1) a review of the study design, (2) general statistical considerations, (3) comprehensive statistical analysis methods for efficacy and safety outcomes, and (4) a list of proposed tables and figures. Any deviation from this SAP will be described and justified in protocol amendments and/or in the CSR, as appropriate. The reader of this SAP is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

# 2 INTRODUCTION

The global diarrheal disease burden remains high with approximately four billion cases estimated to occur annually in all age groups, with the highest incidence among infants and younger children under five years of age. In this age group, enteric infections result in nearly 600,000 deaths each year and extract an enormous physical and economic toll in low-resource countries. Large projects have been developed to combat many of the sanitation and malnutrition needs of the populations living within ETEC endemic areas. While these projects have been associated with a lowering of diarrhea episodes within those regions, incidence rates remain high and have changed very little. In ETEC endemic areas it has been estimated that infants and younger children may experience between two to five symptomatic diarrhea episodes due to ETEC within the first three years of life. Currently ETEC is the most important pathogen, among the primary infectious causes of diarrheal disease, for which there is currently no licensed vaccine.

ETEC has long been a WHO target for vaccine development and remains a WHO priority. The information gained from experimental and clinical studies of the 1$^{st}$ generation vaccine, containing ETEC bacteria expressing common colonization factors mixed with cholera toxin B subunit, suggests that a vaccine formulation containing increased amounts of CF antigens may induce stronger levels of anti ETEC immunity and better protective efficacy. A successful phase I trial in Sweden supports further evaluation of the safety and immunogenicity of ETVAX among younger age-groups in an ETEC endemic area.

This phase I/II clinical study is designed to evaluated the safety, tolerability and immunogenicity of the study vaccine. The study will first test the vaccine with and without dmLT in healthy adults, and then move sequentially into toddlers (24-59 months old), younger children (12-23 months old), and infants (6-11

months old). All participants will receive two oral doses of ETVAX with or without dmLT adjuvant or placebo. Prior to moving to the next age group available safety data will be evaluated and reviewed by the International Centre for Diarrheal Disease Research, Dhaka, Bangladesh (icddr,b) DSMB, after which a recommendation will be made on whether to proceed to the next age group.

## 2.1 Purpose of the Analyses

This Phase I/II trial will serve to assess whether ETVAX is safe and provides mucosal as well as systemic immune responses against the key protective antigens when tested in different age-groups in Bangladesh. This study provides an opportunity to test the safety profile of a mucosal adjuvant, double-mutant LT (dmLT), in adults and children, as well as provides the opportunity to potentially assess the ability of dmLT to further enhance the mucosal and systemic antibody responses to key antigens in the ETVAX vaccine among age groups in developing country sites, like Bangladesh, that have proved refractory to oral immunization with enteric vaccines. In addition, this study also allows for the evaluation of the potential dose-sparing effect of dmLT when combined with a lower dose of vaccine. Finally, this clinical trial is considered an essential study along the critical path of the overall clinical development plan before determining whether the vaccine can be tested for protective efficacy in children in developing countries.

# 3 STUDY OBJECTIVES AND ENDPOINTS

## 3.1 Study Objectives

### 3.1.1 Primary Objective

The primary objective deals with safety and tolerability and is the following:

- To evaluate the safety and tolerability of orally administered ETVAX, containing 4 different inactivated *E. coli* strains over-expressing CFA/I, CS3, CS5 and CS6 and a hybrid LCTBA protein, given along and together with different dosages of dmLT adjuvant in descending age groups in Bangladesh.

### 3.1.2 Secondary Objective

The secondary objectives deal with immunogenicity and are the following:

- To assess vaccine induced IgA antibody responses in lymphocyte secretions by the ALS assay against LTB, CFA/I, CS3, CS5 and CS6 in descending age-groups
- To evaluate vaccine induced fecal secretion IgA (SIgA) antibody responses against CFA/I, CS3, CS5, CS6, O78 LPS and LTB in applicable age-groups in Bangladesh
- To assess vaccine induced plasma IgA antibody responses against LTB, O78 LPS, CFA/I, CS3, CS6 and CS5 and IgG antibody responses against LTB and O78 LPS
- To evaluate vaccine induced ALS IgA responses against O78 LPS (if sample volume allows)
- To assess adjuvant effect of dmLT on vaccine immune response compared to responses when giving vaccine alone in descending age-groups in Bangladesh

## 3.2 Endpoints

### 3.2.1 Primary Endpoints

The primary endpoints deal with safety and tolerability and are the following:

- Proportion (%) of SAEs
- Proportion (%) of AEs
- Proportion (%) of vaccine induced reactogenicity events

### 3.2.2 Secondary Endpoints

The secondary endpoints deal with immunogenicity and are the following:

- Antibody response (>two-fold increase in antibody titers between baseline and post-immunization), Geometric Mean Titer (GMT), and Geometric Mean Fold Rise (GMFR) between baseline and post-immunization to CFA/I, CS3, CS5, CS6 and LTB as measured by ALS IgA
- Antibody response (>two fold increase in antibody titer between baseline and post-immunization), GMT, and GMFR to CFA/I, CS3, CS5, CS6 and LTB as measured by fecal SIgA
- Antibody response (>two-fold increase in antibody titers between baseline and post-immunization), GMT, and GMFR to CFA/I, CS3, CS5, CS6 and LTB as measured by plasma IgA
- Antibody response (>two-fold increase in antibody titers between baseline and post-immunization), GMT, and GMFR to LTB and O78 LPS as measured by plasma IgG
- Antibody response (>two-fold increase in antibody titers between baseline and post-immunization), GMT, and GMFR to O78 LPS as measured by ALS IGA, fecal SIgA, and/or plasma IgA

### 3.2.3 Exploratory Endpoints

The exploratory endpoints deal with immunogenicity and are the following:

- T cell immune responses (proliferation and/or cytokines as measured by flow cytometry)
- Neutralizing antibody geometric mean titers (GMT)
- Avidity of immune responses
- Immunoproteomic profile of vaccine induced antibody responses in plasma or intestinally derived samples

## 3.3 Study Definitions and Derived Variables

The following definitions and derivations will be used in this study:

1. Diarrhea is defined as ≥ 3 unformed or loose stools (mixed liquid and solid components) in a 24 hour period or at least 1 bloody loose or liquid stool or 1-2 liquid stools with at least some dehydration.

2. If a participant meets the definition of diarrhea, the start of the diarrhea episode will be the time of the first unformed stool which contributes to meeting the definition and the end of the diarrhea episode will be the time of the last unformed stool. If there is greater than 24 hours between loose or unformed stools then the illness will stop and a new AE will begin.
3. Mild diarrhea is defined as at least 3 looser than normal stools without dehydration in a 24 hour period.
4. Moderate diarrhea is defined as at least 3 looser than normal stools with dehydration in a 24 hour period.
5. Severe diarrhea is defined as at least 3 looser than normal stools with severe dehydration.
6. The baseline value will be defined as the last value obtained prior to the first vaccination of study product.
7. The reference day will be the day of the first vaccination and will be referred to as Day 1.
8. Study days prior to vaccination will be dependent upon the first dose of the vaccine. If the assessment occurred prior to the first dose, study days will be calculated by taking the date minus the first vaccination date (reference day).
9. Study days occurring on or after the date of vaccination will be dependent upon when the assessment occurred. If the assessment occurred on or after the first vaccination but prior to the second vaccination, study days will be calculated by taking the date minus the first vaccination date (reference day) and adding 1. If the assessment occurred on or after the second vaccination, then study days will be calculated by taking the date minus the second vaccination date and adding 1.
10. Age will be calculated from the date of enrollment and will be presented in whole years for adults and in months for children under 5 years of age (truncated integer).
11. The calculations for GMTs will be performed by taking the anti-log of the arithmetic mean of the $\log_{10}$-transformed titers.
12. Fold increase/rise will be calculated as the following:
    a. For fold rise compared to baseline: ratio of: $\frac{post-immunization\ titer}{pre-immunization\ titer}$
    b. For fold rise of post dose 1compared to post dose 2: ratio of: $\frac{post\ dose\ 2\ titer}{post\ dose\ 1\ titer}$
13. The calculations for geometric fold rises (GMFR) will be performed by taking the anti-log of the difference in log-transformed titers.
14. Antibody response is defined as ≥ two-fold increase in GMFR antibody titers between baseline (pre-immunization titer) and post immunization titer.
15. Prior medications are those medications that started and stopped prior to vaccination.

# 4 INVESTIGATIONAL PLAN

## 4.1 Overall Study Design and Plan

This is a Phase I/II single site, double-blind, randomized, placebo-controlled, dose-escalation, age-descending study that will start testing the vaccine in healthy adults, and move sequentially into toddlers, younger children and infants. The study is designed to have 4 parts. All participants will receive two doses of vaccine with or without dmLT adjuvant on an outpatient basis. Before moving to the next lower age group, available safety data will be evaluated and reviewed by the icddr,b Data Safety Monitoring Board (DSMB), after which they will make a recommendation whether to proceed to the next age group.

The study will have 4 parts; Part A (Adult ages 18-45 years), Part B (Toddlers ages 24-59 months), Part C (Younger Children ages 12-23 months) and Part D (Infants ages 6-11 months). Each participant will receive two doses of either ETVAX with dmLT adjuvant, ETVAX without dmLT adjuvant or Placebo. Each participant will be assessed for reactogenicity for 7 days following dose 1 and dose 2. All participants will be followed for safety for six months after the last vaccination, with a scheduled home visit.

The unblinded study pharmacist or member of the IP formulation team will be aware of group allocation, although he/she will not be able to influence or decide this allocation nor be part of the safety assessment. This will ensure that the study team involved in assessment of safety outcomes, as well as participants, are unaware of the identity of the study vaccine administered. This will help rule out bias at the time of assessment. As the reference product and study vaccines are different in appearance and composition, the vaccinator blind will be maintained through the use of the unblinded study pharmacist or member of the IP formulation team who will prepare the vaccines.

In addition, immunogenicity assessments are planned to assess adjuvant effect of dmLT on vaccine immune responses compared to responses when giving vaccine alone in descending age-groups. The study will seek to establish the safety and optimal dose response of study vaccine within each age-group.

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

This Phase I/II trial will serve to assess whether ETVAX is safe and provides mucosal as well as systemic immune responses against the key protective antigens when tested in different age groups in Bangladesh. This study provides an opportunity to test the safety profile of a mucosal adjuvant in adults and children, as well as provide the opportunity to potentially assess the ability of dmLT to further enhance the mucosal and systemic antibody responses to key antigens in the ETVAX vaccine among age groups in developing country sites, like Bangladesh, that have proved refractory to oral immunization with enteric vaccines. In addition, this study also allows for the evaluation of the potential dose-sparing effect of dmLT when combined with a lower dose of vaccine. Finally, protective efficacy results observed in the VAC 006 trial substantiate the rationale for dmLT inclusion in this vaccine candidate. This clinical trial is considered an essential study along the critical path of the overall clinical development plan before determining whether the vaccine can be tested for protective efficacy in children in developing countries.

## 4.3 Selection of Study Population

This will be a single site study conducted at the Mirpur field site by the icddr,b. The first part (Part A) will enroll a total of 45 adult participants (30 vaccinees and 15 placebos) into one Cohort. The second part (Part B) will enroll a total of 150 toddlers (24-29 months) into 6 separate cohorts to be recruited in step-wise

fashion. Each cohort will enroll 25 toddlers (15 vaccinees and 10 placebos). The third part (Part C) will enroll a total of 100 younger children (12-23 months) into 4 separate cohorts in a step-wise fashion. Each cohort will enroll 25 younger children (15 vaccinees and 10 placebos). The fourth part (Part D) will enroll a total of 200 infants (6-11 months) into 5 separate cohorts to be recruited in a step-wise fashion. Each cohort will enroll 40 infants (30 vaccinees and 10 placebos). Toddlers, younger children and infants will only be enrolled if their parents are fully informed about the study and provide consent for their child's participation.

### 4.3.1 Inclusion Criteria

#### 4.3.1.1 Inclusion Criteria: Part A - Adult

Male and female participants will be eligible for inclusion if ALL of the following apply at the time of screening:

1. Healthy male or female adults 18-45 years old, inclusive.
2. General good health as determined by the screening evaluation no greater than 7 days before enrollment and vaccination.
3. Properly informed about the study, able to understand it and sign or thumb print consent form.
4. Available for the entire period of the study and reachable by study staff throughout the entire follow-up period.
5. Female of childbearing potential willing to take a urine pregnancy test at screening and before the second vaccination. Pregnancy tests must be negative before each vaccination. Females of childbearing potential must agree to use an efficacious hormonal or barrier method of birth control during the study. Abstinence is also acceptable.
6. Informed Consent (signature or thumb print provided, with witness signature).

#### 4.3.1.2 Inclusion Criteria: Parts B, C and D – Toddlers, Younger Children, and Infants

Male and female participants will be eligible for inclusion if ALL of the following apply at the time of screening:

1. Healthy male or female toddlers/younger children/infants ages:
    a) Part B: ≥24 and ≤59 months old toddlers at the time of enrollment.
    b) Part C: ≥12 and <24 months old younger children at the time of enrollment.
    c) Part D: ≥6 and <12 months old infants at the time of enrollment.
2. General good health as determined by the screening evaluation no greater than 7 days before enrollment and vaccination.
3. Parent properly informed about the study, able to understand it and sign or thumb print the informed consent form.
4. Parent and child available for the entire study period of the study and reachable by study staff throughout the entire follow-up period.
5. Informed Consent (signature or thumb of parent, with signature of witness, provided)

#### 4.3.1.3 Continued Inclusion Criteria:

Fulfilment of all of the following continuing eligibility criteria is required for all participants to receive their second vaccination (Day 14).

1. Participant available for study evaluations and reachable by study staff throughout the entire follow-up period.
2. Continued informed consent.
3. Negative urine pregnancy test for females of childbearing potential. Pregnancy tests must be negative before each vaccination. Females of childbearing potential must agree to continue use of an efficacious hormonal or barrier method of birth control during the study. Abstinence is also acceptable (Part A ONLY).

### 4.3.2 Exclusion Criteria

#### 4.3.2.1 Exclusion Criteria: Part A - Adults

Participants with any of the following criteria at study entry will not be eligible for participation:

1. Presence of any significant known systemic disorder (cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, immunological, dermatological, neurological, cancer or autoimmune disease) as determined by medical history and/or physical examination which would endanger the participant's health or is likely to result in non-conformance to the protocol.
2. History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder or presence of a significant medical condition that in the opinion of the Investigator precludes participation in the study. Known or suspected impairment of immunological function based on medical history and physical examination. Clinical evidence of active gastrointestinal illness and acute disease at the time of enrollment.
3. Screening positive with hepatitis B antigen and/or hepatitis C antibodies.
4. Participation in research involving another investigational product (defined as receipt of investigational product) during the 30 days before planned date of first vaccination or concurrently participating in another clinical study at any time during the study period, in which the participant has been or will be exposed to an investigational or a non-investigational product.
5. Clinically significant abnormalities in screening hematology or serum chemistry, as determined by the Study Physician.
6. History of febrile illness within 48 hours prior to vaccination and fever at the time of immunization (fever is defined as a temperature ≥37°C (99.5°F) on axillary, oral, or tympanic measurement).
7. Prior receipt of any cholera (e.g., Dukarol, Shancol) or ETEC vaccine.
8. Prior receipt of a blood transfusion or blood products, including immunoglobulins.
9. Evidence of current illicit drug use or drug dependence.
10. Current use of iron or zinc supplements within the past 7 days; current use of antacids (H2 blockers, omeprazole, OTC agents) or immunosuppressive drug.

11. Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants or interfere with the evaluation of the study objectives.
12. Receipt of antimicrobial drugs for any reason within 14 days before vaccination.
13. History of diarrhea during the 7 days before vaccination (see protocol definition of diarrhea)
14. Culture positive for ETEC, *Shigella V. Cholerae* or *Salmonella* within 7 days before vaccination.
15. Acute disease at the time of enrollment or 3 days prior to enrollment.
16. History of chronic administration (defined as more than 14 days) of immunosuppressant medications, including corticosteroids.

#### 4.3.2.2 Exclusion Criteria: Parts B, C and D – Toddlers, Younger Children, and Infants

1. Presence of any significant known systemic disorder (cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, immunological, dermatological, neurological, cancer or autoimmune disease) as determined by medical history and/or physical examination which would endanger the participant's health or is likely to result in non-conformance to the protocol.
2. History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder or presence of a significant medical condition that in the opinion of the Investigator precludes participation in the study. Known or suspected impairment of immunological function based on medical history and physical examination. Clinical evidence of active gastrointestinal illness and acute disease at the time of enrollment.
3. Screening positive with hepatitis B antigen and/or hepatitis C antibodies.
4. Participation in research involving another investigational product (defined as receipt of investigational product) during the 30 days before planned date of first vaccination or concurrently participating in another clinical study at any time during the study period, in which the participant has been or will be exposed to an investigational or a non-investigational product.
5. Clinically significant abnormalities in screening hematology or serum chemistry, as determined by the Study Physician.
6. History of febrile illness within 48 hours prior to vaccination and fever at the time of immunization (fever is defined as a temperature ≥37°C (99.5°F) on axillary, oral, or tympanic measurement).
7. Prior receipt of any cholera (e.g., Dukarol, Shancol) or ETEC vaccine.
8. Prior receipt of a blood transfusion or blood products, including immunoglobulins.
9. Current use of iron or zinc supplements within the past 7 days; current use of antacids (H2 blockers, omeprazole, OTC agents) or immunosuppressive drug.
10. Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants or interfere with the evaluation of the study objectives.
11. Receipt of antimicrobial drugs for any reason within 14 days before vaccination.
12. History of diarrhea during the 7 days before vaccination (see protocol definition of diarrhea).
13. Culture positive for ETEC, Shigella, V.cholerae, Salmonella or Rotavirus (the latter for all children <5 years of age).

14. Acute disease at the time of enrollment or 3 days prior to enrollment.
15. Known or suspected impairment of immunological function based on medical history and physical examination.
16. Participant's parents/guardians not able, available or willing to accept active weekly follow-up by the study staff.
17. History of chronic administration (defined as more than 14 days) of immunosuppressant medications, including corticosteroids. Infants on inhaled or topical steroids may be permitted to participate in the study.
18. Any medical condition in the parents/infant that, in the judgement of the investigator, would interfere with or serves as a contraindication to protocol adherence or a participant's parents' ability to give informed consent.
19. Medically significant malnutrition, defined as moderate malnutrition (wt-for-ht z-score between -3.0 and -2.0) and severe malnutrition (wt-for-ht z-score <-3.0 or edema).

#### 4.3.2.3 Continued Exclusion Criteria

1. History of diarrhea during the 7 days before vaccination (see Protocol definition of diarrhea).
2. History of febrile illness within 48 hours prior to vaccination and fever at the time of immunization (fever is defined as a temperature ≥37°C (99.5°F) on axillary, oral, or tympanic measurement).
3. Current use of iron or zinc supplements within the past 7 days; current use of antacids (H2 blockers, omeprazole, OTC agents) or immunosuppressive drug.
4. Receipt of antimicrobial drugs for any reason.
5. Non-conformance to the protocol.
6. Culture positive for ETEC, Shigella, V.cholerae, Salmonella or Rotavirus (the latter for all children <5 years of age).
7. Acute disease at the time of vaccination visit or any time during the previous 3 days.

## 4.4 Treatments

### 4.4.1 Treatments Administered

#### 4.4.1.1 Test Vaccine (ETVAX)

A vial of ETVAX vaccine represents a full dose and contains the following:

- *E.Coli* ETEX 21, *E.Coli* ETEX 22, *E.Coli* ETEX 23, *E.Coli* ETEX 21 and LCTB*A* protein.
    - Inactivated *E. coli* ETEX 21
      The *E. coli* ETEX 21 strain was developed using a recombinant plasmid expressing the entire CVA/I operand under a tac promoter as described with the difference that the antibiotic selection marker (ampicillin) was replaced with the gene encoding thymidinylatesynthetase, (thyA) from *V. cholerae*.

- Inactivated *E. coli* ETEX 22
  The *E. coli* ETEX 22 strain was developed using a recombinant plasmid expressing the entire CS3 operand under arns promoter which in turn is under the *lac* operator. The selection system for this plasmid is also based on the *thyA*gene from *V. cholerae.*
- Inactivated *E. coli* ETEX 23
  The *E. coli* ETEX 23 strain was developed using a recombinant plasmid expressing the entire CS5 operand under a tac promoter. The selection system for this plasmid is also based on the *thyA*gene from *V. cholerae.*
- Inactivated *E. coli* ETEX 24
  The *E. coli* ETEX 24 strain was developed using a recombinant plasmid expressing the entire CS6 operand under a tac promoter. The selection system for this plasmid is also based on the *thyA*gene from *V. cholerae.*
- LCTB*A* Protein
  LCTB*A* is a hybrid protein between the B-subunit of the *E.coli* heat-labile enterotoxin (LTB) and the B-subunit of the cholera toxin (CTB). Seven amino acids in the CTB molecule have been replaced by amino acids at the corresponding positions of the LTB molecule. The LCTB*a* encoding DNA was cloned on a plasmid under a *tac promoter.*

#### 4.4.1.2 Oral dmLT Adjuvant

LT(R192G/L211A), or dmLT, is a derivative of wild-type enterotoxienic *Escherichia coli* LT that has been genetically modified by replacing the arginine at amino acid position 192 with glycine and the leucine at amino acid position 211 with alanine. These two amino acid substitutions take place in proteolytic cleavage sites which are critical for activation of the secreted toxin molecules.

### 4.4.2 Method of Assigning Participants to Treatment Groups (Randomization)

The randomization scheme will be generated and maintained by the Statistical Data Coordinating Center (SDCC) at the Emmes Corporation, Rockville, MD. Randomization will occur manually on the day participants are to receive their first study vaccination, after confirmation of eligibility and immediately prior to immunization. The unblinded study pharmacist or member of the IP formulation team will be provided with the treatment assignment codes for preparation of the vaccine or placebo to be given to each participant. The unblinded study pharmacist (or designee) will maintain the treatment code list in a secure place. Each participant's treatment assignment will be entered into the AdvantageEDC$^{SM}$ system at Emmes after product administration has occurred.

Eligible participants were randomized and assigned as shown below. The doses shown in **bold** are the highest safe doses chosen by the IPST. Where appropriate, all tables and figures will report the actual dose received.

- Part A: Adults - 1:1:1 ratio - Cohort A1
  - Full dose ETVAX only
  - Full dose ETVAX + 10 μg dmLT
  - Placebo
- Part B: toddlers aged 24 - 59 months,
  - Cohort B1 - 3:2 ratio
    - 1/4 dose ETVAX only
    - Placebo

  - Cohort B2 - 3:2 ratio
    - 1/2 dose ETVAX only
    - Placebo
  - Cohort B3 - 3:2 ratio
    - Full dose ETVAX only
    - Placebo
  - Cohort B4 - 3:2 ratio
    - **Highest safe dose ETVAX (1/2 dose) + 2.5µg dmLT**
    - Placebo
  - Cohort B5 - 3:2 ratio
    - **Highest safe dose ETVAX (1/2 dose) + 5µg dmLT**
    - Placebo
  - Cohort B6 - 3:2 ratio
    - **Highest safe dose ETVAX (1/2 dose) + 10µg dmLT**
    - Placebo
- Part C: younger children aged 12 - 23 months,
  - Cohort C1 - 3:2 ratio
    - 1/4 dose ETVAX only
    - Placebo
  - Cohort C2 - 3:2 ratio
    - 1/2 dose ETVAX only
    - Placebo
  - Cohort C3 - 3:2 ratio
    - **Highest safe dose ETVAX (1/2 dose) + 2.5µg dmLT**
    - Placebo
  - Cohort C4 - 3:2 ratio
    - **Highest safe dose ETVAX (1/2 dose) + 5µg dmLT**
    - Placebo
- Part D: infants aged 6 - 11 months,
  - Cohort D1 - 3:1 ratio
    - 1/8 dose ETVAX only
    - Placebo
  - Cohort D2 - 3:1 ratio
    - 1/4 dose ETVAX only
    - Placebo
  - Cohort D3 - 3:1 ratio
    - 1/2 dose ETVAX only
    - Placebo
  - Cohort D4 - 3:1 ratio
    - **Highest safe dose ETVAX (1/4 dose) + 2.5µg dmLT**
    - Placebo
  - Cohort D5 - 3:1 ratio
    - **Highest safe dose ETVAX (1/4 dose) + 5µg dmLT**
    - Placebo

### 4.4.3 Blinding

The study and reference vaccines will be prepared and administered by the licensed unblinded pharmacist or member of the IP formulation team. All follow-up safety and efficacy evaluations will be performed by blinded clinic staff.

The unblinded pharmacist will refer to the Treatment Key provided for the trial by Emmes to determine the treatment for the participants. The pharmacist will maintain an open label code (provided by Emmes) under locked/secured conditions and will follow the randomization code.

The protocol contains no explicit provisions for emergency unblinding. The study medical monitor responds to requests for emergency unblinding, and instructs Emmes to release treatment codes only if necessary to ensure that the participant receives appropriate clinical care.

## 4.5 Immunogenicity and Safety Variables

The following section describes the collection of immunogenicity and safety variables. For a detailed schedule of activities refer to Appendix I of the Protocol. For a list of the primary and secondary immunogenicity and safety variables, refer to section 3.2 of the SAP.

### 4.5.1 Safety Variables

The safety variables to be assessed are adverse events (AEs), serious adverse events (SAEs), and multiple clinical safety laboratory measurements [including white blood cells (WBC), hemoglobin (Hgb), platelets, differentials (neutrophils and lymphocytes), alanine aminotransferase (ALT), albumin, total bilirubin and serum creatinine], physical exam, and vital sign parameters. Solicited systemic reactogenicity events within 7 days of each vaccination will be collected. If a solicited sign or symptom has started during the seven days post-vaccination and continues, it will continue to be reported as a reactogenicity symptom. Only when the reactogenicity event is considered an SAE, as defined below, will it be reported on an AE/SAE form in addition to the reactogenicity form. Any symptom starting after seven days post-vaccination will be recorded as an AE. Unsolicited AEs will be collected through the Day 42 visit. SAEs will be collected through six months after the first vaccination or the duration of the study.

#### 4.5.1.1 Reactogenicity Events

Reactogenicity events are adverse events that are common and known to occur following the administration of the study vaccine. These events will be collected in a standard, systematic format using a graded scale based on functional assessment or magnitude of reaction. The reactogenicity adverse events are solicited systemic reactions collected by interviews with the participant/parent/guardian, memory aids and assessed by the site at clinic visits. The systemic symptoms assessed are elevated oral temperature, nausea, vomiting, loose stools, diarrhea, abdominal pain/stomach ache and acute systemic allergic reaction.

#### 4.5.1.2 Unsolicited Adverse Events

An AE is defined as any untoward medical occurrence associated with the use of a vaccine in humans, whether or not considered vaccine related, that occurs during the conduct of a clinical trial. Any change from baseline assessment of clinical status, routine laboratory tests, X-rays, physical examinations, etc., that is considered clinically significant by the PI is considered an AE.

AEs, including non-solicited injection site and systemic reactions not meeting the criteria for "SAEs" will be captured on the appropriate case report form. All AEs will be followed until resolution or stability even when this extends beyond the study-reporting period. Resolution of an AE is defined as the return to pretreatment status or stabilization of the condition with the expectation that it will remain chronic. AEs will be graded for severity and relationship to study product. AEs will also be coded by MedDRA® version 19.1 or higher for preferred term and system organ class.

The study site will assign severity grades to indicate the severity of adverse events and reactions. The severity grading criteria are provided in Appendix II of the Protocol and grades AEs from Mild (Grade 1) to Life Threatening (Grade 4). All AEs leading to death are Grade 5 events. AEs are graded with the worst severity grade during the illness/symptom.

When assessing causality of an AE to study product, the PI should consider whether there is a reasonable possibility that the study product caused the event. Reasonable possibility implies there is evidence to suggest that the study product caused the reported event. An affirmative answer designates the event as a suspected adverse reaction, and the AE is considered "related". If the answer is no, then the AE is considered "unrelated". The causality assessment is made on the basis of the available information at the reporting time point. Assessment of causality can change according to follow-up information.

#### 4.5.1.3 Serious Adverse Events

An SAE, including a serious suspected adverse reaction or serious adverse reaction as determined by the PI or the Sponsor, is any event that results in any of the following outcomes:

- Death;
- Life-threatening adverse event (Life-threatening means that the study participant was, in the opinion of the PI or Sponsor, at immediate risk of death from the event as it occurred);
- Inpatient hospitalization greater than 24 hours or prolongation of existing hospitalization;
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life function, or;
- Congenital abnormality or birth defect;
- Important medical events that may not result in one of the above outcomes but may jeopardize the health of the study participant or require medical or surgical intervention to prevent one of the outcome listed in the above definition of serious event.

All SAEs will be:

- Recorded on the appropriate SAE report form and sent to the Emmes Coordination Center within 24 hours of the site's knowledge of the event.
- Reviewed by the Emmes Medical Monitor and a report written and provided to the PI.
- Reported to the icddr,b DSMB and ERC within 24 hours of the study team becoming aware of the event.
- The Emmes Coordinating Center will notify the Sponsor and the CRO performing site monitoring and will do so simultaneously with the reporting to the clinical database. They will also provide the IPST, the PATH Medical Officer and the Emmes Medical Monitor with listings of all SAEs on an ongoing basis.

- Reviewed and followed to resolution by the PI or a study physician.
- Reported to the WIRB according to the WIRB guidelines and using the WIRB Ten Day Adverse Event Form by PATH.

SAEs will be collected on each participant for 182 days after vaccination.

### 4.5.2 Immunogenicity Variables

Whole blood will be collected at Day 1, Day 7 and Day 19 to assess vaccine induced IgA antibody responses in lymphocyte secretions by the ALS assay against LTB, CFA/I, CS3, CS5, CS6, and 078 LPS (if sample volume allows). Plasma samples will be collected at Screening, Day 7 and Day 19 to assess vaccine induced IgA antibodies by Enzyme linked immunosorbent assay (ELISA) assay against LTB, CFA/I, CS3, CS5, CS6 and 078 LBS and IgG antibodies by ELISA against LTB and 078 LPS. Fecal samples will be collected at Screening, Day 1, Day 7, Day 19 and Day 29 to evaluate vaccine induced fecal SIgA antibody responses against LTB, CFA/I, CS3, CS5, CS6 and 078 LPS. If insufficient specimen volume is obtained in toddlers, younger children and infants, to measure all antigens, then the five primary antigens (LTB, CFA/I, CS3, CS5, and CS6) will be prioritized.

The immunogenicity variables will be analyzed using the following:

- antibody response defined as ≥ 2-fold increase in antibody titers between baseline and post-immunization.
- antibody response defined as ≥ 4-fold increase in antibody titers between baseline and post-immunization.
- geometric mean titer (GMT)
- geometric mean fold rise (GMFR)

For immunogenicity variables, data inferior to the Lower Limit of Quantification (LLOQ) will be replaced by half the detection limit; data superior to the Upper Limit of Quantification (ULOQ) will be replaced by this limit (truncated data). No search for outliers will be performed. However, the logarithmic transformation will be used as appropriate to improve the distributional properties of the data and reduce the impact of potential outliers.

Flow cytometry will be used to induce T cells responses to vaccine antigens. The percentage of T cells responding to vaccine antigens will be defined for each participant by subtracting the proportion of cells responding to uninfected control cells from the percentage responding to vaccine antigens. In addition, neutralizing antibodies to LTB will be measured and analyzed.

Adequate sampling volume may not be obtained, so the following prioritization scheme will be applied to the vaccine antigens according to analysis as specimen volumes allow:

- ALS IgA: LTB > CFA/I> CS3> CS6 > CS5> 078 LPS;
- Fecal SIgA: LTB > CFA/I> CS3> CS6 > CS5> 078 LPS;
- Plasma IgA: LTB > 078 LPS > CFA/I> CS3> CS6 > CS5;
- Plasma IgG: LTB > 078 LPS;
- T cell and other immune responses: LTB > CFA/I > CS3 > CS6 > CS5.

# 5 SAMPLE SIZE CONSIDERATIONS

The sample size for this study was selected to detect frequent adverse events. Given a planned sample size of groups of 15 adults, toddlers, and younger children each receiving one of varying dose levels of ETVAX with or without dmLT, the study will have an approximately 80% and 90% chance of observing at least one serious adverse event or adverse event of special interest for events that occur at a rate of 10.3% and 14.3%, respectively. Additionally, if no serious adverse events are observed in 15 participants, the upper bound of the one-sided 95% confidence interval on the rate of serious adverse event occurrence is approximately 18%.

For infant cohorts with 30 participants per dose group, the study will have an approximately 80% and 90% chance of observing at least one serious adverse event or adverse event of special interest for events that occur at a rate of 5.3% and 7.4%, respectively. If no serious adverse events are observed in 30 participants, the upper bound of the one-sided 95% confidence interval on the rate of serious adverse event occurrence is approximately 9.5%.

For infant cohorts, with 30 participants per group, this study is designed to provide approximately 73% power to detect as low as a 2-fold difference in geometric mean fold rise (post-vaccination / baseline) between comparisons of two groups with varying doses of ETVAX and dmLT levels. This power calculation was based on the variability estimate, log10 standard deviation of 0.6, for CS6 obtained from a previous study of the vaccine in Sweden (VAC 003/OEV-121) and two-sample t-test using the 5% two-sided Type I error rate and 10% drop-out rate.

# 6 GENERAL STATISTICAL CONSIDERATIONS

## 6.1 General Principles

All continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, quartiles and range (maximum and minimum). Where appropriate (e.g., immunogenicity), geometric means and corresponding 95% confidence intervals will be included. The number and percent of participants (based on the population sample size) of observed levels will be reported for all categorical measures. Where appropriate (e.g., immunogenicity and safety outcomes), 95% confidence intervals for the proportion of participants with an event will be included.

In general, all data will be listed, sorted by treatment and participant, and when appropriate by visit number within participant. All summary tables will be structured with a column for each treatment in the order of non-adjuvanted ETVAX, low dose adjuvanted ETVAX, medium dose adjuvanted ETVAX, high dose adjuvanted ETVAX and Placebo and will be annotated with the total population size relevant to specific tables/treatment, including any missing observations.

## 6.2 Timing of Analyses

The final analysis will be performed after the completion of the study. Extensive safety monitoring will be ongoing throughout the study.

## 6.3 Analysis Populations

A tabular listing of all participants, visits, and observations excluded from the safety, full analysis and per protocol populations will be provided in the CSR (see Listing 16.2.3).

### 6.3.1 Enrolled Population

All screened participants who provide informed consent (IC), regardless of the participant's randomization and treatment status in the trial, will be included in the enrolled population.

### 6.3.2 Safety Population

All participants in the enrolled population who receive a study vaccination and have safety data available will be included in the safety population. Treatment groups for safety analysis will be assigned according to the actual treatment received at the first vaccination. If a participant receives mixed doses (e.g., an ETVAX dose without dmLT at Dose 1 and the same ETVAX at Dose 2 with dmLT), the safety data collected after the start of the mixed dosing (e.g., post Dose 2) will be excluded from the analysis. All excluded data will be presented in the data listings. All safety analyses will be performed using this population.

### 6.3.3 Full Analysis Population

All participants in the enrolled population who are randomized, receive a study vaccination, and have pre- and/or post-vaccination immunogenicity measurements will be included in the Full Analysis (FA) Population. This population will serve as the supportive analysis population for the immunogenicity objectives.

Any additional exclusion from the Full Analysis population if warranted (e.g., a significant protocol deviation that is determined to potentially interfere with the vaccine induced immune responses) based on the blinded review of the data will be established and documented before breaking the blind.

### 6.3.4 Per Protocol Population

All participants in the FA population who receive both doses of the same study vaccine and have post second dose and pre-vaccination immunogenicity measurements, with no major protocol or laboratory test standard operating procedure (SOP) violations that are determined to potentially interfere with the immunogenicity assessment of the study vaccine, will be included in the per protocol population.

The specific criteria for exclusion of participants from the PP population will be established before breaking the blind and will be based on the blinded review of protocol violations.

There could potentially be a different per protocol population for each specified sample and antigen type. Participants will be included in the sample and antigen type PP Population if they have a post second dose and pre-vaccination immunogenicity measurement for the specific sample and antigen. These populations will serve as the primary analysis populations for the immunogenicity objectives.

## 6.4 Covariates and Subgroups

There is no a priori plan to summarize the immunogenicity or safety endpoints for covariates. The protocol is set up as a descending age-group study, so each age-group will be summarized separately. The 4 age groups to be analyzed are adults, toddlers (24-59 months), younger children (12-23 months), and infants (6-11 months). The protocol does not define any additional subgroup analyses.

## 6.5 Missing Data

In general, all missing data will be treated as missing completely at random and no imputation will be performed except for the safety endpoints as described below. Non-analyzable data (e.g., due to major protocol violations) will be documented in the deviations.

If some safety data are available for a participant in the FA population, but respective secondary endpoint related data are missing, then the participant will be included in the safety analysis and data will be treated as follows for immediate AEs, unsolicited AEs and serious adverse events (SAEs).

1. If Severity is missing for any AE, then it will be considered as an AE of maximum severity (Grade 3) "Severe", unless it is captured as SAE.
2. If "Relationship" is missing, then it will be considered as "Related" to the vaccine administered.
3. If, for Start date, the day of event/condition is missing due to any adverse event, then it will be imputed as the date of last dose of study vaccine.
4. If the Stop date of an adverse event is missing, then it will be treated as ongoing.

For solicited adverse events, the following assumptions will be made:

1. If dates are missing, but symptoms are reported, then the day post vaccination will be used to calculate the date of the symptom.
2. If a symptom is not reported at any time through Day 7, then no imputation for missing data will be performed. The data will be summarized as not reported on the tables.

## 6.6 Interim Analyses and Data Monitoring

Extensive safety monitoring will be provided for this protocol. The PI and/or designated site staff will be responsible for continuous close safety monitoring of all study participants and for alerting the Sponsor if unexpected concerns arise or stopping criteria are met.

### 6.6.1 Safety Oversight

A Data and Safety Monitoring Board (DSMB) will be formed by the Ethical Review Committee (ERC) to evaluate and assess the safety of study participants. In addition, an Independent Protocol Safety Team (IPST) will be formed for the study and will carry out the safety and clinical evaluation of the icddr,b. Moreover there will be a team comprised of the study physician, the Emmes medical monitor, the PI, and the Medical Officer from PATH for evaluation of the study at different intervals during the study.

Before enrolling participants in subsequent cohorts within an age group, the safety data from the previous cohort(s) will be evaluated and reviewed by the IPST. These data include, but are not limited to, physical examinations, vital signs, and solicited reactogenicity symptoms. The IPST will convene after each cohort

within an age group to review data through Day 4 after the second vaccine administration and make a recommendation to the Sponsor on whether to proceed to the initiation of the following cohort.

The DSMB will be composed of 3-4 members, two of which are nominated by the ERC chairperson. The PI also has the option of nominating 1-2 members with therapeutic expertise. The DSMB meets before study initiation, prior to age de-escalation, and after the study closeout. The PI can also request a DSMB meeting depending upon the study complexity or in light of study concerns. The DSMB will advise the PI of its findings and provide recommendations. The DSMB will review all unanticipated problems involving risk to the participants or others, serious adverse events, and all participant deaths associated with the protocol. The PI will inform the Emmes Medical Monitor and the PATH Medical Officer in detail about the discussions of those meetings.

### 6.6.2 Study Pause

Study pause is defined as a decision to cease, temporarily or definitely, enrollment and all vaccinations. Study pause or final cessation of vaccinations will not eliminate any safety follow-up procedures specified by the protocol. The Sponsor will pause vaccinations in the study if the IPST, DSMB or protocol team including the PATH Medical Officer and Emmes Medical Monitor, determines that study hold criteria have been met, or in the event of any other safety concerns.

The following study pause rules will automatically pause or halt further vaccinations until the protocol team consisting of the PI, study physician, independent medical monitor, PATH Medical Officer and Emmes Medical Monitor, has performed a review. However participants already enrolled will continue to be followed for safety during the pause. These pause rules refer to suspected adverse reactions and will be triggered automatically if any of the events described below are met during the conduct of the study:

- One participant death from Day 0 to Day 42, unless judged definitely unrelated to vaccination;
- One participant with a serious AE (SAE) judged as definitely or probably related to vaccine;
- >2 participants in a cohort with the same ≥ grade 3 (severe) solicited AE within three days following vaccination judged as definitely or probably related to vaccine;
- >2 participants in a cohort with the same ≥ grade 3 (severe) abnormal clinical monitoring laboratory value (7 days following vaccination) judged as definitely or probably related to vaccine;
- >2 participants in a cohort with the same ≥ grade 3 (severe) AE judged as definitely or probably related to vaccine.

### 6.6.3 Interim Analysis and Future Planning

Early final analysis of each Part when all cohorts within the Part have completed the primary safety and immunogenicity follow-up (Day 43, 28 days post last vaccination) may be performed to facilitate the decisions external to the study conduct. The unblinded analysis will be performed by an independent statistician who is not involved in the conduct of the study after all data have been cleaned and locked through Day 43 follow-up for all participants in each Part. Analysis will be presented in group unblinded fashion and no individual listing will be generated. These analyses would not otherwise alter the course of the trial and blinded status of the study for investigators and study participants until the completion of the study.

## 6.7 Multicenter Studies

This is a single site study.

## 6.8 Multiple Comparisons/Multiplicity

This is an exploratory study in descending age groups. Due to the exploratory nature of all of the statistical comparisons for immunogenicity endpoints, there will not be an adjustment for multiple comparisons across the entire study. However, within each immunogenicity endpoint for each age group, the Holm-Bonferroni correction for multiple testing will be applied to control the multiple comparisons associated with multiple treatment groups. It is acknowledged that there will be inflated Type I errors (i.e., inflated false statistical significances) from performing multiple unadjusted comparisons.

# 7 SUMMARY OF STUDY PARTICIPANTS

## 7.1 Participant Disposition

Screened participants who were ineligible for enrollment in the study will be presented by inclusion and exclusion criteria and other reasons for ineligibility (Table 14.1.1(a)(b)(c)(d)). The composition of analysis populations, including reasons for participant exclusion, by treatment group, is presented in Table 14.1.2(a)(b)(c)(d).

The disposition of participants in the study will be tabulated by treatment group and overall (Table 14.1.3(a)(b)(c)(d)). This table will show the number of participants screened, enrolled, received first vaccination, received second vaccination, completed Visit 7 (Day 43), completed follow-up, in FA Population and in PP population.

A flowchart presenting the disposition of study participants, adapted from the CONSORT statement [32] will be included (Figure 14.1.1(a)(b)(c)(d)). The flowchart includes the number of participants eligible, enrolled and randomized, lost to follow-up, and analyzed, by treatment group.

A listing of participants who discontinued or terminated early from the study and who were excluded from the Safety population, the FA population and the PP population will be included in Listings 16.2.1(a)(b)(c)(d) and 16.2.3(a)(b)(c)(d), respectively.

## 7.2 Protocol Deviations

A summary of protocol deviations will be presented by the deviation category, reason, and treatment group in Table 10.2.1(a)(b)(c)(d). This table will provide both the number of participants and the number of deviations for each category and treatment group.

All participant-specific and non-participant-specific protocol deviations will be included as data listings (Listings 16.2.2.1(a)(b)(c)(d) and 16.2.2.2(a)(b)(c)(d), respectively).

## 7.3 Demographic and Other Baseline Characteristics

Summaries of sex, ethnicity, and race will be presented by treatment group and overall in Tables 14.1.4.1 (a)(b)(c)(d) for all participants in the Safety population. Participants may self-designate as belonging to more than one race or may refuse to identify a race, the latter reflected in the CRF as "No" to each racial option. Participants belonging to more than one race will be categorized as multi-racial and

participants refusing to identify with a race will be classified as unknown on the table. Age will be summarized in years for adults and in months for toddlers, younger children and infants. Age, height and weight will be summarized by treatment group and overall in Tables 14.1.4.2(a)(b)(c)(d).

Individual participant listings will be presented for all demographic and baseline characteristics (Listings 16.2.4.1(a)(b)(c)(d)).

## 7.4 Concurrent Illnesses and Medical Conditions

All current illnesses and past pre-existing medical conditions will be MedDRA coded using MedDRA dictionary version 19.1 or higher. Summaries of participant's pre-existing medical conditions will be presented by MedDRA® SOC and treatment group (Tables 14.1.5(a)(b)(c)(d)) for all participants in the Safety population.

Individual data listings will be presented for all pre-existing medical conditions (Listings 16.2.4.2(a)(b)(c)(d)).

## 7.5 Measurements of Treatment Compliance

All participants were to receive 2 doses of study product administered in the clinic. Any participants who were enrolled but did not receive both vaccinations will be presented by treatment group and by site as part of the participant disposition table (Table 14.1.3(a)(b)(c)(d)). A summary of the dates of vaccination will be presented by treatment group in Table 14.1.6(a)(b)(c)(d)).

# 8 IMMUNOGENICITY EVALUATION

The secondary and exploratory immunogenicity analyses are based on the ALS assay, ELISA assay and fecal assays. Whole blood and plasma specimens will be collected for immunogenicity assessments at Screening, Day 7 and Day 19. Fecal specimens will be collected for immunogenicity assessments at Screening, Day 1, Day 7, Day 19 and Day 29. All immunogenicity analyses will be conducted using the FA and the PP populations, unless they are the same. The number of participants in a population may vary by antigen and assay type as only participants contributing assessments will be included in the population for a specific antigen and assay. Individual participant data listings of immunogenicity will be presented in Listings 16.2.6.1(a)(b)(c)(d) - 16.2.6.3(a)(b)(c)(d) for ALS, fecal, and plasma, respectively.

Pairwise comparisons between each dose of the vaccine without dmLT, and each vaccine co-administered with dmLT adjuvant dose and placebo will be performed for each age-group: adults, toddlers (24-59 months), younger children (12-23 months), and infants (6-11 months). In addition, pairwise comparisons will be made between the combined vaccine without dmLT group and the combined vaccine with dmLT as well as comparisons of these two group with placebo.

Due to the hypothesis generating nature of multiple statistical comparisons for immunogenicity associated with multiple endpoints for this age and dose escalating study, all estimations will be carried out using a two-sided 5% Type I error rate. For each immunogenicity endpoint and antigen analyzed, a Holm's-Bonferroni correction will be applied to determine significance.

## 8.1 ALS Antibodies

For ALS IgA, tables will be presented by antigen in the order of priority as specimen volumes allow. The order of the antigens will be: LTB, CFA/I, CS3, CS6, CS5, and 078 LPS. Immune responses as measured by ALS IgA after each vaccination (Day 7 and Day 19 samples) will be evaluated by the following:

- the percentage of participants achieving an antibody response after the first vaccination (i.e., antibody response is calculated using baseline and Day 7 sample) for LTB, CFA/I, CS3, CS6, CS5 and 078 LPS (if sample available);
- the percentage of participants achieving an antibody response after the second vaccination (i.e., antibody response is calculated using baseline and Day 19 sample) for LTB, CFA/I, CS3, CS6, CS5 and 078 LPS (if sample available);
- the percentage of participants achieving an antibody response after either vaccination (i.e., antibody response observed after either vaccination) for LTB, CFA/I, CS3, CS6, CS5 and 078 LPS (if sample available);
- the geometric mean titer (GMT) of CFA/I, CS3, CS5, CS6, LTB, and 078 LPS (if sample available) at screening and after each vaccination;
- the geometric mean fold rise (GMFR) of CFA/I, CS3, CS5, CS6, LTB and 078 LPS (if sample available) between doses (baseline to post-dose 1 and post-dose 1 to post-dose 2) and from baseline to post-dose 2.

### 8.1.1 Antibody Response

Percentages of participants with an antibody response at Day 7, Day 19 or at any time point will be calculated along with the corresponding two-sided exact (Clopper-Pearson) binomial 95% CIs. For each antigen, the proportion of participants with an antibody response at Day 7, Day 19 or at any time point will be compared between each pairwise comparison of ETVAX dose level, ETVAX + dmLT dose level, and placebo using Fisher's exact test.

Tables 14.2.1.1 (a)(b)(c)(d) - 14.2.1.2 (a)(b)(c)(d) will summarize the antibody response and 95% CIs for each time period and treatment group by antigen for the FA population and the PP population, respectively. In addition, a Fisher's exact test for each treatment group comparison will be presented for each time period and antigen as shown in Tables 14.2.2.1 (a)(b)(c)(d) - 14.2.2.2(a)(b)(c)(d) for the FA population and the PP population, respectively.

### 8.1.2 Geometric Mean Titer

For the ALS titer, antibody levels will be summarized on the original scale by treatment group at Screening, Day 7 and Day 19. The number of observations, geometric mean titer (GMT) and geometric 95% CI of the GMT will be reported. For ALS titers reported as below the assay Lower Level of Quantification (LLoQ), a value of half of the LLoQ will be used. The GMT will be calculated as the antilog of the mean of the logarithms of the ALS titer. The 95% CIs of the GMT will be based on the t-distribution to provide population estimates and will be presented as the antilog. Two-sided 95% CIs for the ratios of post dose 1 and post dose 2 GMTs between two treatment groups will be constructed using the log normal distribution. The log values will be used to construct a CI using the t-distribution for the mean difference between all

pair-wise comparisons. The mean difference and the corresponding CI limits will then be exponentiated to obtain the GMT ratio and the corresponding CI. Each pairwise comparison will be performed on the log-normal assay responses using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the ratio of GMT.

Tables 14.2.3.1 (a)(b)(c)(d) - 14.2.3.2 (a)(b)(c)(d) will summarize the GMTs and 95% CIs for each antigen and treatment group for the FA population and the PP population, respectively. The ratio of GMTs, 95% CI of ratio of GMTs and t-test will be summarized in Tables 14.2.4.1 (a)(b)(c)(d) - 14.2.4.2 (a)(b)(c)(d). Reverse cumulative distribution curves for the ALS titer after the first vaccination (Day 7) and the second vaccination (Day 19) will be presented by treatment group for each antigen analyzed as depicted in Figures 14.2.5.1 (a)(b)(c)(d) - 14.2.5.2 (a)(b)(c)(d).

### 8.1.3 Geometric Mean Fold Rise

For the ALS titer, the fold rise will be calculated after the first vaccination (post vaccination 1 antibody titer/baseline antibody titer), after the second vaccination (post vaccination 2 antibody titer/baseline antibody titer), and after the second vaccination compared to first vaccination (post vaccination 2 antibody titer/post vaccination 1 antibody titer). The number of observations, GMFR and 95% confidence intervals for the GMFR will be reported. The GMFR will be calculated as the antilog of the mean of the logarithms of the calculated fold rise. The 95% CIs for the GMFR will be based on the t-distribution to provide population estimates and will be presented as the antilog. Pairwise comparisons of the logs of the fold-rise will be performed using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the fold rise.

Tables 14.2.6.1 (a)(b)(c)(d) - 14.2.6.2 (a)(b)(c)(d) will summarize the GMFRs and 95% CIs for the GMFRs for each antigen and treatment group for the FA population and the PP population, respectively. In addition, the p-value from a t-test for each treatment group comparison will be presented for each time period and antigen as shown in Tables 14.2.7.1 (a)(b)(c)(d) - 14.2.7.2(a)(b)(c)(d) for the FA population and the PP population, respectively.

### 8.1.4 In-Text Summaries

In-text Tables 11.3.1(a)(b)(c)(d) will summarize the antibody response from baseline to the post dose 2 (Day 19) time point and the GMT and 95% CI of GMT at the post dose 2 (Day 19) time point by treatment group and antigen strain for the ALS assay. In addition, the number of antigens where an antibody response is observed at the post dose 2 (Day 19) time point will be calculated per participant. The five primary antigens will be LTB, CFA/I, CS3, CS5 and CS6. If a participant has specimen results for all 5 antigens at both baseline and post dose 2 (Day 19), they will be included in a summary presented as Table 11.3.2.1 (a)(b)(c)(d). An analysis of variance will be used to determine if the number of antigens responding is different between treatment groups.

Additional tables will be created following the same structure and analyses as above for the following groups:

- Participants with specimen results for at least 4 antigens at both baseline and post dose 2 (Day 19), Table 11.3.2.2 (a)(b)(c)(d).

- Participants with specimen results for at least 3 antigens at both baseline and post dose 2 (Day 19), Table 11.3.2.3 (a)(b)(c)(d).
- Participants with specimen results for at least 2 antigens at both baseline and post dose 2 (Day 19), Table 11.3.2.4 (a)(b)(c)(d).

## 8.2 Fecal Antibodies

Immune responses as measured by Fecal SIgA after each dose (Day 7 and Day 19 samples) and at Day 29 will be evaluated by the following:

- the proportion of participants achieving an antibody response after the first vaccination (i.e., antibody response is calculated using baseline and Day 7 sample) for CFA/I, CS3, CS5, CS6, LTB and 078 LPS (if sample available);
- the proportion of participants achieving an antibody response after the second vaccination (i.e., antibody response is calculated using baseline and Day 19 sample) for CFA/I, CS3, CS5, CS6, LTB and 078 LPS (if sample available);
- the proportion of participants achieving an antibody response after the second vaccination at Day 29 (i.e., antibody response is calculated using baseline and Day 29 sample) for CFA/I, CS3, CS5, CS6, LTB and 078 LPS (if sample available);
- the proportion of participants achieving an antibody response after either vaccination (i.e., antibody response observed after either vaccination) for CFA/I, CS3, CS5, CS6, LTB and 078 LPS (if sample available);
- the geometric mean titer (GMT) of CFA/I, CS3, CS5, CS6, LTB, and 078 LPS (if sample available) at screening, after the first dose (Day 7), after the second dose (Day 19) and after the second dose (Day 29);
- the geometric mean fold rise (GMFR) of CFA/I, CS3, CS5, CS6, LTB and 078 LPS(if sample available) between doses (baseline to post-dose 1 and post-dose 1 to post-dose 2 [Day 19]), from baseline to post-dose 2 (Day 19), and from baseline to post-dose 2 (Day 29).

### 8.2.1 Antibody response

Percentages of participants with an antibody response at Day 7, Day 19, Day 29 or at any time point will be calculated along with the corresponding two-sided exact (Clopper-Pearson) binomial 95% CIs. For each antigen, the proportion of participants with an antibody response at Day 7, Day 19, Day 29 or at any time point will be compared between each pairwise comparison of ETVAX dose level, ETVAX + dmLT dose level, and placebo using Fisher's exact test.

Tables 14.2.8.1 (a)(b)(c)(d) - 14.2.8.2 (a)(b)(c)(d) will summarize the antibody response and 95% CIs for each time period and treatment group by antigen for the FA population and the PP population, respectively. In addition, a Fisher's exact test for each treatment group comparison will be presented for each time period and antigen as shown in Tables 14.2.9.1 (a)(b)(c)(d) - 14.2.9.2(a)(b)(c)(d) for the FA population and the PP population, respectively.

### 8.2.2 Geometric Mean Titer

For the Fecal SIgA titers, antibody levels will be summarized on the original scale by treatment group at Screening, Day 7, Day 19 and Day 29. The number of observations, geometric mean titer (GMT) and geometric 95% CI of the GMT will be reported. For Fecal titers below the LLoQ, an arbitrary value of half of the LLoQ will be used. The GMT will be calculated as the antilog of the mean of the logarithms of the Fecal titer. The 95% CIs of the GMT will be based on the t-distribution to provide population estimates and will be presented as the antilog. Two-sided 95% CIs for the ratios of post dose 1 and post dose 2 GMTs between two treatment groups will be constructed using the log normal distribution. The log values will be used to construct a CI using the t-distribution for the mean difference between all pair-wise comparisons. The mean difference and the corresponding CI limits will then be exponentiated to obtain the GMT ratio and the corresponding CI. Each pairwise comparison will be performed on the log-normal assay responses using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the ratio of GMT.

Tables 14.2.10.1 (a)(b)(c)(d) - 14.2.10.2 (a)(b)(c)(d) will summarize the GMTs and 95% CIs for each antigen and treatment group for the FA population and the PP population, respectively. The ratio of GMTs, 95% CI of ratio of GMTs and t-test will be summarized in Tables 14.2.11.1 (a)(b)(c)(d) - 14.2.11.2 (a)(b)(c)(d). Reverse cumulative distribution curves for the ALS titer after the first vaccination (Day 7) and the second vaccination (Day 19 and Day 29) will be presented by treatment group for each antigen analyzed as depicted in Figures 14.2.12.1 (a)(b)(c)(d) - 14.2.12.2 (a)(b)(c)(d).

### 8.2.3 Geometric Mean Fold Rise

For the Fecal SIgA titer, the fold rise will be calculated after the first vaccination (post vaccination 1 (Day 7) antibody titer/baseline antibody titer), after the second vaccination (post vaccination 2 (Day 19) antibody titer/baseline antibody titer), after the second vaccination (post vaccination 2 (Day 29) antibody titer/baseline antibody titer), and after the second vaccination compared to first vaccination (post vaccination 2 (Day 19) antibody titer/post vaccination 1 (Day 7) antibody titer). The number of observations, GMFR and 95% confidence intervals for the GMFR will be reported. The GMFR will be calculated as the antilog of the mean of the logarithms of the calculated fold rise. The 95% CIs for the GMFR will be based on the t-distribution to provide population estimates and will be presented as the antilog. Pairwise comparisons of the logs of the fold-rise will be performed using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the fold rise.

Tables 14.2.13.1 (a)(b)(c)(d) - 14.2.13.2 (a)(b)(c)(d) will summarize the GMFRs and 95% CIs for the GMFRs for each antigen and treatment group for the FA population and the PP population, respectively. In addition, the p-value from a t-test for each treatment group comparison will be presented for each time period and antigen as shown in Tables 14.2.14.1 (a)(b)(c)(d) - 14.2.14.2(a)(b)(c)(d) for the FA population and the PP population, respectively.

### 8.2.4 In-Text Summaries

In-text Tables 11.3.3(a)(b)(c)(d) will summarize the antibody response from baseline to the post dose 2 (Day 19) time point and the GMT and 95% CI of GMT at the post dose 2 (Day 19) time point by treatment group and antigen strain for the fecal secretion assay. In addition, the number of antigens where an antibody response is observed at the post dose 2 (Day 19) time point will be calculated per participant. The five primary antigens will be LTB, CFA/I, CS3, CS5 and CS6. If a participant has specimen results for all 5 antigens at both baseline and post dose 2 (Day 19), they will be included in summary presented on Table 11.3.4 (a)(b)(c)(d). A Fisher's exact test will be used to compare each vaccine treatment against placebo.

The comparisons will be:

- the number of participants with 5 antigens responding versus those with 4 or less responding,
- the number of participants with 4 or more antigens responding versus those with 3 or less responding,
- the number of participants with 3 or more antigens responding versus those with 2 or less responding,
- the number of participants with 2 or more antigens responding versus those with 1 or less responding, and
- the number of participants with 1 or more antigens responding versus those with no antigens responding.

## 8.3 Plasma ELISA Antibodies

For ELISA IgA, tables will be presented by antigen in the order of priority as specimen volumes allow. The order of the antigens will be: LTB, 078 LPS, CFA/I, CS3, CS6, and CS5. For ELISA IgG, only LTB and 078S LPS will be analyzed. Immune responses as measured by ELISA IgA and IgG after each vaccination (Day 7 and Day 19 samples) will be evaluated by the following:

- the percentage of participants achieving an IgA antibody response after the first vaccination (i.e., antibody response is calculated using baseline and Day 7 sample) for LTB, 078 LPS, CFA/I, CS3, CS6, and CS5;
- the percentage of participants achieving an IgA antibody response after the second vaccination (i.e., antibody response is calculated using baseline and Day 19 sample) for LTB, 078 LPS, CFA/I, CS3, CS6, and CS5;
- the percentage of participants achieving an IgA antibody response after either vaccination (i.e., antibody response observed after either vaccination) for LTB, 078 LPS, CFA/I, CS3, CS6, and CS5;
- the IgA geometric mean titer (GMT) of LTB, 078 LPS, CFA/I, CS3, CS6, and CS5 at screening and after each vaccination;
- the IgA geometric mean fold rise(GMFR) of LTB, 078 LPS, CFA/I, CS3, CS6, and CS5 between doses (baseline to post-dose 1 and post-dose 1 to post-dose 2) and from baseline to post-dose 2.

- the percentage of participants achieving an IgG antibody response after the first vaccination (i.e., antibody response is calculated using baseline and Day 7 sample) for LTB and 078 LPS (if sample available);
- the percentage of participants achieving an IgG antibody response after the second vaccination (i.e., antibody response is calculated using baseline and Day 19 sample) for LTB and 078 LPS;
- the percentage of participants achieving an IgG antibody response after either vaccination (i.e., antibody response observed after either vaccination) for LTB and 078 LPS;
- the IgG geometric mean titer (GMT) of LTB and 078 LPS at screening and after each vaccination;
- the IgG geometric mean fold rise(GMFR) of LTB and 078 LPS between doses (baseline to post-dose 1 and post-dose 1 to post-dose 2) and from baseline to post-dose 2.

### 8.3.1 Antibody response

Percentages of participants with an antibody response at Day 7, Day 19 or at any time point will be calculated along with the corresponding two-sided exact (Clopper-Pearson) binomial 95% CIs. For each antigen, the proportion of participants with an antibody response at Day 7, Day 19 or at any time point will be compared between each pairwise comparison of ETVAX dose level, ETVAX + dmLT dose level, and placebo using Fisher's exact test.

Tables 14.2.15.1 (a)(b)(c)(d) - 14.2.15.2 (a)(b)(c)(d) for IgA and Tables 14.2.17.1(a)(b)(c)(d) - 14.2.17.2 (a)(b)(c)(d) for IgG will summarize the antibody response and 95% CIs for each time period and treatment group by antigen for the FA population and the PP population, respectively. In addition, a Fisher's exact test for each treatment group comparison will be presented for each time period and antigen as shown for IgA in Tables 14.2.16.1 (a)(b)(c)(d) - 14.2.16.2(a)(b)(c)(d) and for IgG in Tables 14.2.18.1 (a)(b)(c)(d) - 14.2.18.2(a)(b)(c)(d) for the FA population and the PP population, respectively.

### 8.3.2 Geometric Mean Titer

For the ALS titer, antibody levels will be summarized on the original scale by treatment group at Screening, Day 7 and Day 19. The number of observations, geometric mean titer (GMT) and geometric 95% CI of the GMT will be reported. For ALS titers below the LLoQ, an arbitrary value of half of the LLoQ will be used. The GMT will be calculated as the antilog of the mean of the logarithms of the ALS titer. The 95% CIs of the GMT will be based on the t-distribution to provide population estimates and will be presented as the antilog. Two-sided 95% CIs for the ratios of post dose 1 and post dose 2 GMTs between two treatment groups will be constructed using the log normal distribution. The log values will be used to construct a CI using the t-distribution for the mean difference between all pair-wise comparisons. The mean difference and the corresponding CI limits will then be exponentiated to obtain the GMT ratio and the corresponding CI. Each pairwise comparison will be performed on the log-normal assay responses using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the ratio of GMT.

Tables 14.2.19.1 (a)(b)(c)(d) - 14.2.19.2 (a)(b)(c)(d) for IgA and Tables 14.2.21.1 (a)(b)(c)(d) - 14.2.21.2 (a)(b)(c)(d) for IgG will summarize the GMTs and 95% CIs for each antigen and treatment group for the FA population and the PP population, respectively. The ratio of GMTs, 95% CI of ratio of GMTs and t-test will be summarized in Tables 14.2.20.1 (a)(b)(c)(d) - 14.2.20.2 (a)(b)(c)(d) for IgA and

Tables 14.2.22.1 (a)(b)(c)(d) - 14.2.22.2 (a)(b)(c)(d) for IgG. Reverse cumulative distribution curves for the ELISA titer after the first vaccination (Day 7) and the second vaccination (Day 19) will be presented by treatment group for each antigen analyzed as depicted in Figures 14.2.23.1 (a)(b)(c)(d) - 14.2.23.2 (a)(b)(c)(d) for IgA and Tables 14.2.24.1 (a)(b)(c)(d) - 14.2.24.2 (a)(b)(c)(d) for IgG.

### 8.3.3 Geometric Mean Fold Rise

For the ELISA titer, the fold rise will be calculated after the first vaccination (post vaccination 1 antibody titer/baseline antibody titer), after the second vaccination (post vaccination 2 antibody titer/baseline antibody titer), and after the second vaccination compared to first vaccination (post vaccination 2 antibody titer/post vaccination 1 antibody titer). The number of observations, GMFR and 95% confidence intervals for the GMFR will be reported. The GMFR will be calculated as the antilog of the mean of the logarithms of the calculated fold rise. The 95% CIs for the GMFR will be based on the t-distribution to provide population estimates and will be presented as the antilog. Pairwise comparisons of the logs of the fold-rise will be performed using a t-test. If the values deviate from the log normal distribution, a non-parametric method (i.e., Wilcoxon) may be used for the analysis of the fold rise.

Tables 14.2.25.1 (a)(b)(c)(d) - 14.2.25.2 (a)(b)(c)(d) for IgA and Tables 14.2.27.1(a)(b)(c)(d) - 14.2.27.2 (a)(b)(c)(d) for IgG will summarize the GMFRs and 95% CIs for the GMFRs for each antigen and treatment group for the FA population and the PP population, respectively. In addition, the p-value from a t-test for each treatment group comparison will be presented for each time period and antigen as shown in Tables 14.2.26.1 (a)(b)(c)(d) - 14.2.26.2(a)(b)(c)(d) for IgA and Tables 14.2.28.1 (a)(b)(c)(d) - 14.2.28.2(a)(b)(c)(d) for IgG for the FA population and the PP population, respectively.

### 8.3.4 In-text summaries

In-text Tables 11.3.5(a)(b)(c)(d) will summarize the antibody response from baseline to the post dose 2 (Day 19) time point and the GMT and 95% CI of GMT at the post dose 2 (Day 19) time point by treatment group and antigen strain for the plasma ELISA IgA assay. In addition, the number of antigens where an antibody response is observed at the post dose 2 (Day 19) time point will be calculated per participant. The five primary antigens will be LTB, CFA/I, CS3, CS5 and CS6. If a participant has specimen results for all 5 antigens at both baseline and post dose 2 (Day 19), they will be included in summary presented on Table 11.3.6 (a)(b)(c)(d). A Fisher's exact test will be used to compare each vaccine treatment against placebo.

The comparisons will be:

- the number of participants with 5 antigens responding versus those with 4 or less responding,
- the number of participants with 4 or more antigens responding versus those with 3 or less responding,
- the number of participants with 3 or more antigens responding versus those with 2 or less responding,
- the number of participants with 2 or more antigens responding versus those with 1 or less responding,
- the number of participants with 1 or more antigens responding versus those with 0 antigens responding.

### 8.4 T-cell Immune Responses

Individual T-cell and other immune responses will be listed by participant and antigen in Listings 16.2.6.4(a)(b)(c)(d). A more detailed description of analyses will be provided after it is known if and what specimens will be available for analysis.

## 9 SAFETY EVALUATION

### 9.1 Adverse Events

All safety analyses will be presented using the Safety population.

Any medical condition that is present at the time that the participant is screened will be considered baseline and not reported as an AE, unless it worsens in severity or increases in frequency during the study. When calculating the incidence of solicited and unsolicited adverse events (i.e., on a per participant basis), each participant will be counted once and any repetitions of solicited and unsolicited adverse events within a participant will be ignored; the denominator will be the total population size. All adverse events reported will be included in the summaries and analyses.

#### 9.1.1 Solicited Events and Symptoms

Solicited adverse events will be collected pre-vaccination, 60 minutes post-vaccination and then daily for 7 days after vaccination and graded on a scale of 0 (absent), 1 (mild), 2 (moderate) and 3 (severe). Solicited events include: elevated oral temperature, nausea, vomiting, loose stools, diarrhea, abdominal pain/stomach ache, and acute systemic allergic reaction. Adults will have all events collected. Toddlers (24 - 59 months) will have all events except nausea collected and Younger Children (12 - 23 Months) and Infants (6 - 11 months) will only have oral temperature, vomiting, loose stools, diarrhea and acute systemic allergic reaction collected.

The proportion of participants reporting at least one solicited adverse event within 7 days of any vaccination will be summarized for each solicited adverse event and for any solicited adverse event. The 95% CI calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option) will be presented (Tables 14.3.1.1(a)(b)(c)(d)).

For each solicited adverse event and for any solicited adverse event, the maximum severity over 7 days after each vaccination will be summarized for the Safety population. The number and percentage of participants reporting each event will be summarized for each treatment group by the maximum severity. For each event the denominator is the number of participants with non-missing data for the specific event (Tables 14.3.1.2(a)(b)(c)(d)).

The number and percentage of participants reporting any solicited adverse event and reporting each individual solicited adverse event will be summarized for each day post vaccination for each vaccination by Treatment group (Tables 14.3.1.3(a)(b)(c)(d)) and severity. The percent of participants reporting any solicited event will be displayed graphically in a bar chart in Figures 14.3.1.4(a)(b)(c)(d)).

Fisher's exact test will be used to compare the proportion of participants with solicited reactogenicity events between each of the vaccine arms with the placebo arms. In addition, the vaccine arms without dmLT will be combined, the vaccine arms with dmLT will be combined and all vaccine arms will be combined and each will be compared to placebo. The results will be summarized in Tables 14.3.1.5(a)(b)(c)(d).

A logistic regression analysis will be presented to look at the proportion of vomiting after any ETVAX dose, with covariates for sex, age group (i.e., cohort's B, C and D), dose and adjuvant in the model. The age group categories will correspond with cohorts B, C and D: 6-11 months, 12-23 months, and 24-59 months, respectively. Results will be summarized for all vaccinated children in Table 14.3.1.6.1 and all children in Table 14.3.1.6.2.

The primary purpose of the statistical comparisons is to screen out potential solicited reactogenicity events that need further clinical evaluation. Therefore, they are not considered formal statistical hypothesis tests and it is acknowledged that there will be inflated Type I errors (i.e., inflated false statistical significances) from performing multiple unadjusted comparisons.

Solicited adverse events by participant will be presented in Listings 16.2.7.1(a)(b)(c)(d).

### 9.1.2 Unsolicited Adverse Events

The proportion of participants reporting at least one unsolicited adverse event will be summarized by MedDRA system organ class and preferred term for each treatment group and overall. Denominators for percentages are the number of participants in the Safety population. A 95% CI calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option) will be presented for each MedDRA system organ class and preferred term (Tables 14.3.1.7(a)(b)(c)(d))

Unsolicited adverse events by participant will be presented in Listings 16.2.7.2(a)(b)(c)(d).

The following summaries for unsolicited adverse events will be presented by treatment group:

- Participant level summary of maximum severity and relationship to study product by MedDRA SOC and PT (Tables 14.3.1.8.1(a)(b)(c)(d));
- Participant level summary of related unsolicited events by maximum severity, MedDRA SOC and PT (Tables 14.3.1.8.2(a)(b)(c)(d));
- Participant incidence of unsolicited adverse events over time by MedDRA SOC and PT (Days 1-8, Days > 8) (Tables 14.3.1.9.1(a)(b)(c)(d));
- Participant incidence of related unsolicited adverse events over time by MedDRA SOC and PT (Days 1-8, Days > 8) (Tables 14.3.1.9.2(a)(b)(c)(d));
- Total frequency of adverse events over time by MedDRA SOC and PT (Days 1-8, Days > 8) (Tables 14.3.1.10(a)(b)(c)(d));
- Participant listing of non-serious adverse events of moderate or greater severity (Tables 14.3.2.2(a)(b)(c)(d));
- Bar chart of the frequency of events for non-serious adverse events by maximum severity and MedDRA SOC (Figures 14.3.1.11(a)(b)(c)(d));
- Bar chart of the percent of participants reporting a non-serious adverse event by maximum severity and MedDRA SOC (Figures 14.3.1.12(a)(b)(c)(d));
- Bar chart of the frequency of any adverse event by maximum severity (Figures 14.3.1.13(a)(b)(c)(d));
- Bar chart of the percent of participants of any adverse event by maximum severity (Figures 14.3.1.14(a)(b)(c)(d));
- Bar chart of the frequency of non-serious adverse events by relationship to treatment and MedDRA SOC (Figures 14.3.1.15(a)(b)(c)(d));

- Bar chart of the percent of participants of non-serious adverse events by relationship to treatment and MedDRA SOC (Figures 14.3.1.16(a)(b)(c)(d));
- Bar chart of the frequency of any adverse event by relationship to treatment (Figures 14.3.1.17(a)(b)(c)(d)).
- Bar chart of the percent of participants experiencing any adverse event by relationship to treatment (Figures 14.3.1.18(a)(b)(c)(d)).

## 9.2 Deaths, Serious Adverse Events and other Significant Adverse Events

A listing of deaths and SAEs (Tables 14.3.2.1(a)(b)(c)(d)) will be presented including Participant ID, Age (years for adults and months for toddlers, younger children, and infants) Adverse Event Description, Adverse Event Onset Date/End Date, Last Days Post Dose, Reason Reported as an SAE, Relationship to Treatment, Outcome, and Duration of Event (days).

## 9.3 Pregnancies

If any adult participants in the Safety population become pregnant during the study, every attempt will be made to follow these participants to completion of pregnancy to document the outcome, including information regarding any complications with pregnancy and/or delivery. If more than 5 pregnancies are reported, a table summarizing the total pregnancies, number of live births, and number of spontaneous abortions, elective abortions or still births by treatment will be presented. In addition, a listing of all pregnancies and outcomes will be presented (Listing 16.2.11(a)).

## 9.4 Clinical Laboratory Evaluations

Safety clinical laboratory evaluations will be performed at Screening and at Day 7 at the designated site laboratory and will include: hemoglobin (HgB), white blood cells (WBC), platelet counts, neutrophils, lymphocytes, alanine transaminase (ALT), and creatinine. Albumin and total bilirubin will be collected at the Screening visit only. In addition, screening laboratory tests will include serum HCG pregnancy tests for females of childbearing potential only, and screening for HIV, HCV and HBV.

The summary tables will include all laboratories collected at Screening and Day 7 and which have toxicity grades. These include HGB, platelet counts, WBC, ALT, and creatinine. For each part, the distribution of laboratory results by severity, scheduled study day and treatment group will be presented in Tables 14.3.4.1(a)(b)(c)(d) for any laboratory parameter and each individual laboratory parameter. The observed and change from screening measurements will be summarized using descriptive statistics including mean, standard deviation, median, 25th and 75th percentiles, minimum and maximum values by scheduled study day, for each laboratory parameter in Tables 14.3.4.2(a)(b)(c)(d). Graphical presentation of changes in laboratory values will be presented using box plots as depicted in Figures 14.3.4.3(a)(b)(c)(d), for each laboratory parameter. Unscheduled or repeated follow-up tests for medical or safety reasons will be listed and included in the maximum post-baseline row on the summary tables, but will otherwise be excluded from tabular and graphical summaries.

Participant visits with abnormal laboratory results, Grade 1 severity or higher, will be presented in Tables 14.3.4.4(a)(b)(c)(d).

Listings of all individual clinical laboratory results will be provided by hematology, biochemistry and serology (Listings 16.2.8.1(a)(b)(c)(d)-16.2.8.3(a)(b)(c)(d), respectively). Results meeting the protocol defined toxicity of Grade 1 or higher will have their grade provided in parentheses after the result.

## 9.5 Vital Signs and Physical Evaluations

Vital sign measurements include respiration rate, heart rate and oral temperature, along with height and weight (length for infants and younger children) at Screening. Vital signs were assessed at Screening, Day 1, Day 7, Day 15, Day 19, Day 28, Day 42 and Day 182. Respiration rate and heart rate will be summarized over time graphically using box plots for participants in the Safety population (Figures 14.3.5.1(a)(b)(c)(d)). Listings of all individual vital sign measurements will be provided in Listings 16.2.9.1(a)(b)(c)(d).

Physical Examinations were performed at Screening, and Day 43. Any abnormal or change in physical examination data from Screening will be listed for each participant by visit and treatment group. The following body systems will be assessed: HEENT, Skin, Lymph Nodes, Neck, Chest, Abdomen, Neurological, and Musculoskeletal (Listings 16.2.9.2(a)(b)(c)(d)).

## 9.6 Concomitant Medications

Concomitant medications are those medications taken at the same time or after vaccination. Prior medications are those medications that were started and stopped prior to vaccination. Both prior and concomitant medications will be classified according to a standardized drug code. The use of prior and concomitant medications taken during the study will be summarized by medication name and treatment group (Tables 14.3.6(a)(b)(c)(d)).

Individual participant listings will be presented for all prior and concurrent medications (Listings 16.2.10(a)(b)(c)(d)).

# 10 REPORTING CONVENTIONS

P-values ≥0.001 and ≤0.999 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001"; p-values greater than 0.999 will be reported as "> 0.999". The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Proportions will be presented as two decimal places; values <0.01 will be presented as "<0.01". Percentages will be reported to the nearest whole number; values < 1% will be presented as "<1". Estimated parameters, not on the same scale as raw observations (e.g., regression coefficients) will be reported to 3 significant figures.

# 11 TECHNICAL DETAILS

SAS version 9.3 or above will be used to generate all tables, figures and listings.

# 12 SUMMARY OF CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

The primary and secondary immunogenicity endpoints are defined as a 2-fold increase or more in antibody titers between baseline and post-immunization. In addition, each table will also display the results of a 4-fold increase in antibody titers.

# 13 REFERENCES

# 14 APPENDIX I: TABLES, FIGURES, and DATA LISTINGS

**General Programming Guidelines:**

- This study has 4 parts and each of the tables and figures is separated into the different parts:
  - a: Adults
  - b: Toddlers (24 - 59 Months)
  - c: Younger Children (12 - 23 Months)
  - d: Infants (6 - 11 Months)
- For Treatments specified in the shells as "ETVAX (highest safe dose)", this corresponds with the highest safe dose during the dose escalation for the specified part of the study.
- Since this is a dose escalation study, some of the planned doses might not be administered if safety issues arise. Only treatments administered for a "Part" will be summarized.
- For immunogenicity tables, vaccine antigens will be prioritized according to specimen volume. This means that all antigens might not be analyzed and this can vary by each part of the study.

## 14.1 TABLES, FIGURES

**TABLE 10.2.1a:**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Adults**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

**TABLE 10.2.1a: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Adults**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

Note: ICF=Informed Consent Form.

[Implementation: Only include the Deviation categories and reasons reported in the study.]

**TABLE 10.2.1b:**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Toddlers (24- 59 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

**TABLE 10.2.1b: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Toddlers (24- 59 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

Note: ICF=Informed Consent Form.

**TABLE 10.2.1b: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Toddlers (24- 59 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

**TABLE 10.2.1b: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Toddlers (24- 59 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

Note: ICF=Informed Consent Form

**TABLE 10.2.1c:**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Young Children (12- 23 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

**TABLE 10.2.1c: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Young Children (12- 23 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

Note: ICF=Informed Consent Form.

**TABLE 10.2.1c: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Young Children (12- 23 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

**TABLE 10.2.1c: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Young Children (12- 23 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

Note: ICF=Informed Consent Form

**TABLE 10.2.1d:**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Infants (6-11 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

**TABLE 10.2.1d: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Infants (6-11 Months)**

| Category | Deviation Reason | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x | x | x |

Note: ICF=Informed Consent Form.

**TABLE 10.2.1d: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Infants (6-11 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Eligibility/enrollment | Any type | x | x | x | x | x | x |
| | Did not meet inclusion criterion | x | x | x | x | x | x |
| | Met exclusion criterion | x | x | x | x | x | x |
| | ICF not signed prior to study procedures | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Vaccination administration schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Missed treatment administration | x | x | x | x | x | x |
| | Delayed treatment administration | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Follow-up visit schedule | Any type | x | x | x | x | x | x |
| | Out of window visit | x | x | x | x | x | x |
| | Missed visit/visit not conducted | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |
| Treatment administration | Any type | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

**TABLE 10.2.1d: continued**
**Distribution of Protocol Deviations by Category, Reason, and Treatment Group - Infants (6-11 Months)**

| Category | Deviation Reason | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|
| | | # of Parti. | # of Dev. | # of Parti. | # of Dev. | # of Parti. | # of Dev. |
| Protocol procedure/assessment | Any type | x | x | x | x | x | x |
| | Incorrect version of ICF signed | x | x | x | x | x | x |
| | Blood not collected | x | x | x | x | x | x |
| | Urine not collected | x | x | x | x | x | x |
| | Stool not collected | x | x | x | x | x | x |
| | Other specimen not collected | x | x | x | x | x | x |
| | Too few aliquots obtained | x | x | x | x | x | x |
| | Specimen result not obtained | x | x | x | x | x | x |
| | Required procedure not conducted | x | x | x | x | x | x |
| | Required procedure done incorrectly | x | x | x | x | x | x |
| | Study product temperature excursion | x | x | x | x | x | x |
| Blinding policy/procedure | Any type | x | x | x | x | x | x |
| | Treatment unblinded | x | x | x | x | x | x |
| | Other | x | x | x | x | x | x |

Note: ICF=Informed Consent Form

**TABLE 11.3.1.1:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 7 post dose 1, by Antigen and Treatment Group - Adults**

| | Placebo (N=XX) | | | ETVAX Full Dose (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline

[b]GMT = Geometric mean titer.

**TABLE 11.3.1.2:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 19 (5 days post dose 2), by Antigen and Treatment Group - Adults**

**TABLE 11.3.1.3:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion after either dose, by Antigen and Treatment Group - Adults**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.1.4:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 7 post-dose 1, by Antigen and Treatment Group - Toddlers (24-59 Months)**

| | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | ETVAX Full Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline

[b]GMT = Geometric mean titer.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline

[b]GMT = Geometric mean titer.

**TABLE 11.3.1.5:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 19 (5 days post-dose 2), by Antigen and Treatment Group - Toddlers (24-59 Months)**

**TABLE 11.3.1.6:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion after either dose, by Antigen and Treatment Group - Toddlers (24-59 Months)**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.1.7:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 7 post dose 1, by Antigen and Treatment Group - Young Children (12-23 Months)**

| | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline. [b]GMT = Geometric mean titer.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline. [b]GMT = Geometric mean titer.

**TABLE 11.3.1.8:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 19 (5 days post dose 2), by Antigen and Treatment Group - Young Children (12-23 Months)**

**TABLE 11.3.1.9:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion after either dose, by Antigen and Treatment Group - Young Children (12-23 Months)**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.1.10:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 7 post dose 1, by Antigen and Treatment Group - Infants (6-11 Months)**

| | Placebo (N=XX) | | | ETVAX 1/8 Dose (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline

[b]GMT = Geometric mean titer.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS3 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS6 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CS5 | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

**TABLE 11.3.1.11:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion on Day 19 (5 days post dose 2), by Antigen and Treatment Group - Infants (6-11 Months)**

**TABLE 11.3.1.12:**
**Descriptive Statistics and Analysis of IgA responses in Antibody Lymphocyte Secretion after either dose, by Antigen and Treatment Group - Infants (6-11 Months)**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.2.1:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Adults**

**Participants with ALS Specimens for all 5 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX Full Dose + 10 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | |
| 5 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 4 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 3 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | |
| 5 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 4 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 3 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | 0.xxx |
| | | | | |
| Number of Participants[c] | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for all 5 antigens (LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.2:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with ALS Specimens for all 5 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +10 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for all 5 antigens (LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.3:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with ALS Specimens for all 5 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for all 5 antigens (LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.4:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with ALS Specimens for all 5 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/8 Dose (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | |
| 5 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for all 5 antigens (LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.5:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Adults**

**Participants with ALS Specimens for at least 4 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX Full Dose + 10 µg dmLT (N=XX) n (%) | All Participants (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | |
| 4 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 3 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | |
| 4 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 3 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 4 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.6:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with ALS Specimens for at least 4 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +10 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 4 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.7:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with ALS Specimens for at least 4 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 4 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.8:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with ALS Specimens for at least 4 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/8 Dose (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | |
| 4 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 4 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.9:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Adults**

**Participants with ALS Specimens for at least 3 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX Full Dose + 10 µg dmLT (N=XX) n (%) | All Participants (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | |
| 3 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | |
| 3 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 3 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.10:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with ALS Specimens for at least 3 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +10 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 3 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.11:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with ALS Specimens for at least 3 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 3 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.12:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with ALS Specimens for at least 3 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/8 Dose (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | |
| 3 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 3 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.13:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Adults**

**Participants with ALS Specimens for at least 2 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX Full Dose + 10 µg dmLT (N=XX) n (%) | All Participants (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | |
| 2 antigens | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| 1 antigen | xx (%) | xx (%) | xx (%) | xx (%) | 0.xxx |
| | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 2 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.14:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with ALS Specimens for at least 2 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX Full Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +10 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 2 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.2.15:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with ALS Specimens for at least 2 antigens**

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| | | | | | | |
| Number of Participants[c] | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 2 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

## TABLE 11.3.2.16:
## Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Antibody Lymphocyte Secretion Specimens by Treatment Group - Infants (6 - 11 Months)

### Participants with ALS Specimens for at least 2 antigens

| Frequency of Participants Responding to at least: | Placebo (N=XX) n (%) | ETVAX 1/8 Dose (N=XX) n (%) | ETVAX 1/4 Dose (N=XX) n (%) | ETVAX 1/2 Dose (N=XX) n (%) | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) n (%) | ETVAX (highest safe dose) +5 µg dmLT (N=XX) n (%) | P-value[b] |
|---|---|---|---|---|---|---|---|
| **≥ 2-Fold Response[a]** | | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| **≥ 4-Fold Response[a]** | | | | | | | |
| 2 antigens | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| 1 antigen | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | xx (xx%) | 0.xxx |
| Number of Participants[c] | xx | xx | xx | xx | xx | xx | |

[a] A responder is a participant with a response after dose 1 (Day 7) or dose 2 (Day 19).
[b] Fisher's exact 2-tail test comparing the treatment groups, adjusted for multiple comparisons using the Holm-Bonferroni method.

[c] Participants with Antibody Lymphocyte Secretion specimens for at least 2 antigens (from LTB, CFA/I, CS3, CS5, and CS6) included in the table.

**TABLE 11.3.3.1:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7 post dose 1, by Antigen and Treatment Group - Adults**

**TABLE 11.3.3.2:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 19 (5 days post dose 2), by Antigen and Treatment Group – Adults**

**TABLE 11.3.3.3:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 28, by Antigen and Treatment Group – Adults**

**TABLE 11.3.3.4:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7, Day 19, or Day 28, by Antigen and Treatment Group - Adults**

These tables will be in the same format as **Table 11.3.1.1**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.3.5:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7 post-dose 1, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.3.6:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 19 (5 days post-dose 2), by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.3.7:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 28, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.3.8:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7, Day 19, or Day 28, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

These tables will be in the same format as **Table 11.3.1.4**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.3.9:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7 post dose 1, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.3.10:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 19 (5 days post dose 2), by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.3.11:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 28, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.3.12:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7, Day 19, or Day 28, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

These tables will be in the same format as **Table 11.3.1.7**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.3.13:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7 post-Dose 1, by Antigen and Treatment Group - Infants (6 - 11 Months)**

**TABLE 11.3.3.14:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 19 (5 days post-Dose 2), by Antigen and Treatment Group - Infants (6 - 11 Months)**

**TABLE 11.3.3.15:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 28, by Antigen and Treatment Group - Infants (6 - 11 Months)**

**TABLE 11.3.3.16:**
**Descriptive Statistics and Analysis of IgA responses in Fecal Secretion on Day 7, Day 19, or Day 28, by Antigen and Treatment Group - Infants (6 - 11 Months)**

These tables will be in the same format as **Table 11.3.1.10**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.4.1:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.1**

**TABLE 11.3.4.2:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.2**

**TABLE 11.3.4.3:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.3**

**TABLE 11.3.4.4:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.4**

For these tables, a responder is a participant with a response after dose 1 (Day 7), dose 2 (Day 19) or on Day 28.

**TABLE 11.3.4.5:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.5**

**TABLE 11.3.4.6:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.6**

**TABLE 11.3.4.7:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.7**

**TABLE 11.3.4.8:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.8**

For these tables, a responder is a participant with a response after dose 1 (Day 7), dose 2 (Day 19) or on Day 28.

**TABLE 11.3.4.9:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.9**

**TABLE 11.3.4.10:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.10**

**TABLE 11.3.4.11:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.11**

**TABLE 11.3.4.12:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.12**

For these tables, a responder is a participant with a response after dose 1 (Day 7), dose 2 (Day 19) or on Day 28.

**TABLE 11.3.4.13:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.13**

**TABLE 11.3.4.14:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.14**

**TABLE 11.3.4.15:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.15**

**TABLE 11.3.4.16:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Fecal Secretion Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.16**

For these tables, a responder is a participant with a response after dose 1 (Day 7), dose 2 (Day 19) or on Day 28.

**TABLE 11.3.5.1:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on Day 7 post-dose 1, by Antigen and Treatment Group - Adults**

**TABLE 11.3.5.2:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on Day 19 (5 days post-dose 2), by Antigen and Treatment Group - Adults**

**TABLE 11.3.5.3:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Adults**

Same format as **Tables 11.3.1.1 to 11.3.1.3**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.5.4:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on Day 7 post-dose 1, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.5.5:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on Day 19 (5 days post-dose 2), by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.5.6:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens after Either Dose, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

Same format as **Tables 11.3.1.4 to 11.3.1.6**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.5.7:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on day 7 post-dose 1, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.5.8:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on day 19 (5 days post-dose 2), by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.5.9:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

Same format as **Tables 11.3.1.7 to 11.3.1.9**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.5.10:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on day 7 post-dose 1, by Antigen and Treatment Group - Infants (6 - 11 Months)**

**TABLE 11.3.5.11:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens on day 19 (5 days post-dose 2), by Antigen and Treatment Group - Infants (6 - 11 Months)**

**TABLE 11.3.5.12:**
**Descriptive Statistics and Analysis of IgA Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Infants (6 - 11 Months)**

Same format as **Tables 11.3.1.10 to 11.3.1.12**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.6.1:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.1**

**TABLE 11.3.6.2:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.2**

**TABLE 11.3.6.3:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.3**

**TABLE 11.3.6.4:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for all 5 antigens**

Same format as **Table 11.3.2.4**

**TABLE 11.3.6.5:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.5**

**TABLE 11.3.6.6:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.6**

**TABLE 11.3.6.7:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.7**

**TABLE 11.3.6.8:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 4 antigens**

Same format as **Table 11.3.2.8**

**TABLE 11.3.6.9:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.9**

**TABLE 11.3.6.10:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.10**

**TABLE 11.3.6.11:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.11**

**TABLE 11.3.6.12:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 3 antigens**

Same format as **Table 11.3.2.12**

**TABLE 11.3.6.13:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group – Adults**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.13**

**TABLE 11.3.6.14:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Toddlers (24 - 59 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.14**

**TABLE 11.3.6.15:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Young Children (12 - 23 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.15**

**TABLE 11.3.6.16:**
**Frequency of IgA Responders Against Different Numbers of Vaccine Antigens in Plasma Specimens by Treatment Group - Infants (6 - 11 Months)**

**Participants with Fecal Secretion Specimens for at least 2 antigens**

Same format as **Table 11.3.2.16**

**TABLE 11.3.7.1:**
**Descriptive Statistics and Analysis of IgG Responses in PlasmaSpecimens, by Antigen and Treatment Group - Adults**

| Antigen | Placebo (N=XX) | | | ETVAX Full Dose (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| **Day 7 post-dose 1** | | | | | | | | | | | | |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| **Day 19 (5 days post-dose 2)** | | | | | | | | | | | | |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| **After either dose[c]** | | | | | | | | | | | | |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a] Fold Rise is calculated from baseline. [b] GMT = Geometric mean titer. [c] Based on the maximum post-vaccination titer.

**TABLE 11.3.7.2:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 7 post-dose 1, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

| | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | ETVAX Full Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a] Fold Rise is calculated from baseline. [b] GMT = Geometric mean titer. [c] Based on the maximum post-vaccination titer.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a] Fold Rise is calculated from baseline. [b] GMT = Geometric mean titer. [c] Based on the maximum post-vaccination titer.

**TABLE 11.3.7.3:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 19 (5 days post-dose 2), by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

**TABLE 11.3.7.4:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Toddlers (24 - 59 Months)**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.7.5:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 7 post-dose 1, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

| | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline. [b]GMT = Geometric mean titer.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| Antigen | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | ≥ 4 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| CFA/I | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) | xx (xx.x) | xx (xx.x) | xx.x (xx.x, xx.x) |

[a]A Fold Rise is calculated from baseline. [b]GMT = Geometric mean titer.

**TABLE 11.3.7.6:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 19 (5 days post-dose 2), by Antigen and Treatment Group - Young Children (12 - 23 Months)**

**TABLE 11.3.7.7:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Young Children (12 - 23 Months)**

Note: after either dose, fold rise at any visit and GMT are based on the maximum post-vaccination titer per participant.

**TABLE 11.3.7.8:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 7 post-dose 1, by Antigen and Treatment Group - Infants (6-11 Months)**

| Antigen | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) |

| Antigen | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|
| | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) | ≥ 2 Fold[a] n (%) | GMT[b] (95% CI) |
| LTB | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) |
| 078 LPS | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) | xx (xx%) | xx.x (xx.x, xx.x) |

[a]A 2 Fold Rise is calculated from baseline to post dose 2 (Day 19).

[b]GMT = Geometric mean titer. This is calculated at post dose 2 (Day 19).

**TABLE 11.3.7.9:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens on day 19 (5 days post-dose 2), by Antigen and Treatment Group - Infants (6-11 Months)**

**TABLE 11.3.7.10:**
**Descriptive Statistics and Analysis of IgG Responses in Plasma Specimens after either dose, by Antigen and Treatment Group - Infants (6-11 Months)**

Note: for the last table, a response is ≥2-fold rise at any visit and GMT is based on the maximum post-vaccination titer per participant

**FIGURE 14.1.1(a): CONSORT Flow Diagram - Adults**

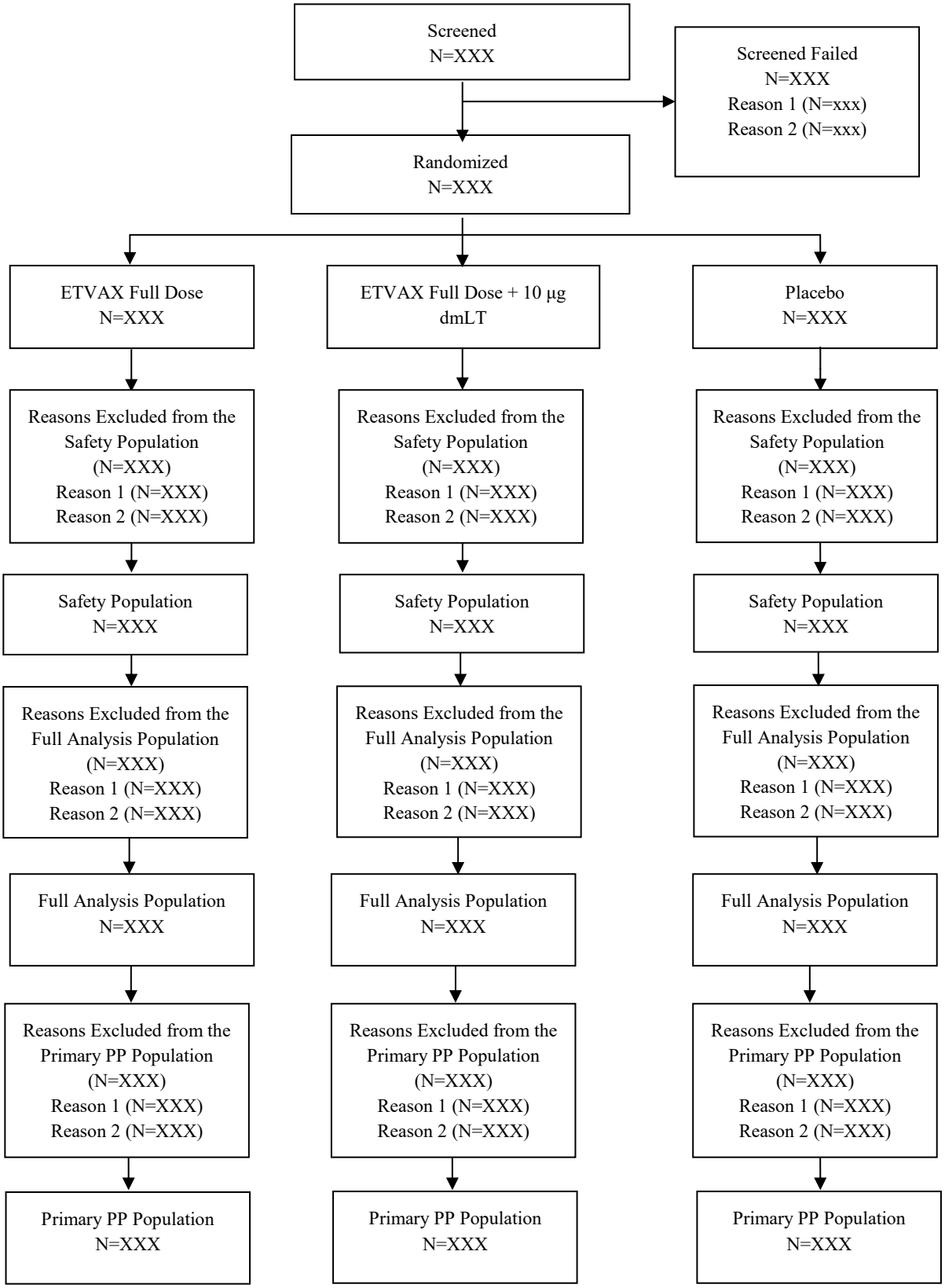


**FIGURE 14.1.1(b): CONSORT Flow Diagram - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.1.1a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

**FIGURE 14.1.1(c): CONSORT Flow Diagram - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.1.1a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.1.1(d): CONSORT Flow Diagram - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.1.1a - except use treatment groups: ETVAX 1.75mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

## TABLE 14.1.1(a):
## Ineligibility Summary of Screen Failures - Adults

| Inclusion/ Exclusion Category | Inclusion/Exclusion Criterion | Number of Times Item Marked Ineligible |
|---|---|---|
| Any | Any inclusion/exclusion criterion | X |
| Inclusion | Any inclusion criterion | X |
| | Healthy male or female adults aged 18 to 45 years | X |
| | General good health as established at screening | X |
| | Properly informed about the study, able to understand and sign or thumb print the informed consent form | X |
| | Available for entire period of study and reachable by study staff throughout the entire follow-up period. | X |
| | Negative pregnancy test, if applicable | X |
| | Agrees to adequate contraception, if applicable | X |
| | Informed Consent signed or thumb print and witnessed | X |
| | | |
| Exclusion | Any exclusion criterion | X |
| | Presence of any significant known systemic disorder | X |
| | History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder | X |
| | Screening positive with hepatitis B antigen and/or hepatitis C antibodies | X |
| | Use of other experimental agents within 30 days prior or after vaccination | X |
| | Clinically significant abnormalities in screening hematology or serum chemistry | X |
| | Prior receipt of any cholera or ETEC vaccine | X |
| | Prior receipt of a blood transfusion or blood products including immunoglobulins | X |
| | Evidence of current illicit drug use or drug dependence | X |
| | Current use of iron or zinc supplements in 7 days prior to vaccination, current use of antacids or immunosuppressive drugs | X |
| | Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants | X |
| | Receipt of antimicrobial drugs for any reason within 14 days of vaccination | X |
| | History of diarrhea during the 7 days prior to vaccination | X |
| | Culture positive for ETEC, *Shigella, V. Cholerae or Salmonella* within 7 days of vaccination | X |
| | Acute disease at the time of enrollment or 3 days prior to enrollment | X |
| | History of chronic administration of immunosuppressant medications | X |
| | | |
| Other | Other | X |

## TABLE 14.1.1(b):
## Ineligibility Summary of Screen Failures - Toddlers (24 - 59 Months)

| Inclusion/ Exclusion Category | Inclusion/Exclusion Criterion | Number of Times Item Marked Ineligible |
|---|---|---|
| Any | Any inclusion/exclusion criterion | X |
| Inclusion | Any inclusion criterion | X |
| | Healthy male or female toddler aged ≥24 and ≤59 months at enrollment | X |
| | General good health as established at screening | X |
| | Parent properly informed about the study, able to understand and sign or thumb print the informed consent form | X |
| | Parent and child available for the entire study period of study and reachable by study staff throughout the entire follow-up period. | X |
| | Informed Consent signed or thumb print and witnessed | X |
| | | |
| Exclusion | Any exclusion criterion | X |
| | Presence of any significant known systemic disorder | X |
| | History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder | X |
| | Screening positive with hepatitis B antigen and/or hepatitis C antibodies | X |
| | Use of other experimental agents within 30 days prior or after vaccination | X |
| | Clinically significant abnormalities in screening hematology or serum chemistry | X |
| | History of febrile illness wihtin 48 hours prior to vaccinatin and fever at the time of immunization) | |
| | Prior receipt of any cholera or ETEC vaccine | X |
| | Prior receipt of a blood transfusion or blood products including immunoglobulins | X |
| | Current use of iron or zinc supplements in 7 days prior to vaccination, current use of antacids or immunosuppressive drugs | X |
| | Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants | X |
| | Receipt of antimicrobial drugs for any reason within 14 days of vaccination | X |
| | History of diarrhea during the 7 days prior to vaccination | X |
| | Culture positive for ETEC, *Shigella, V. Cholerae, Salmonella* or Rotavirus within 7 days of vaccination | X |
| | Acute disease at the time of enrollment or 3 days prior to enrollment | X |
| | Known or suspected impairment of immunological function | X |
| | Participant's parents/guardians not able, available or willing to accept weekly follow-up by study staff | X |
| | History of chronic administration of immunosuppressant medications | X |
| | Any medical condition in the parents/infants that, in the judgment of the investigator, would interfere with the study | X |
| | Medically significant malnutrition | X |
| | | |
| Other | Other | X |

## TABLE 14.1.1(c):
## Ineligibility Summary of Screen Failures - Young Children (12 - 23 Months)

| Inclusion/ Exclusion Category | Inclusion/Exclusion Criterion | Number of Times Item Marked Ineligible |
|---|---|---|
| Any | Any inclusion/exclusion criterion | X |
| Inclusion | Any inclusion criterion | X |
| | Healthy male or female young child aged ≥12 and < 24 months at enrollment | X |
| | General good health as established at screening | X |
| | Parent properly informed about the study, able to understand and sign or thumb print the informed consent form | X |
| | Parent and child available for the entire study period of study and reachable by study staff throughout the entire follow-up period. | X |
| | Informed Consent signed or thumb print and witnessed | X |
| | | |
| Exclusion | Any exclusion criterion | X |
| | Presence of any significant known systemic disorder | X |
| | History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder | X |
| | Screening positive with hepatitis B antigen and/or hepatitis C antibodies | X |
| | Use of other experimental agents within 30 days prior or after vaccination | X |
| | Clinically significant abnormalities in screening hematology or serum chemistry | X |
| | History of febrile illness wihtin 48 hours prior to vaccinatin and fever at the time of immunization) | |
| | Prior receipt of any cholera or ETEC vaccine | X |
| | Prior receipt of a blood transfusion or blood products including immunoglobulins | X |
| | Current use of iron or zinc supplements in 7 days prior to vaccination, current use of antacids or immunosuppressive drugs | X |
| | Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants | X |
| | Receipt of antimicrobial drugs for any reason within 14 days of vaccination | X |
| | History of diarrhea during the 7 days prior to vaccination | X |
| | Culture positive for ETEC, *Shigella, V. Cholerae, Salmonella* or Rotavirus within 7 days of vaccination | X |
| | Acute disease at the time of enrollment or 3 days prior to enrollment | X |
| | Known or suspected impairment of immunological function | X |
| | Participant's parents/guardians not able, available or willing to accept weekly follow-up by study staff | X |
| | History of chronic administration of immunosuppressant medications | X |
| | Any medical condition in the parents/infants that, in the judgment of the investigator, would interfere with the study | X |
| | Medically significant malnutrition | X |
| | | |
| Other | Other | X |

## TABLE 14.1.1(d):
## Ineligibility Summary of Screen Failures - Infants (6 - 11 Months)

| Inclusion/ Exclusion Category | Inclusion/Exclusion Criterion | Number of Times Item Marked Ineligible |
|---|---|---|
| Any | Any inclusion/exclusion criterion | X |
| Inclusion | Any inclusion criterion | X |
| | Healthy male or female infant aged ≥6 and < 11 months at enrollment | X |
| | General good health as established at screening | X |
| | Parent properly informed about the study, able to understand and sign or thumb print the informed consent form | X |
| | Parent and child available for the entire study period of study and reachable by study staff throughout the entire follow-up period. | X |
| | Informed Consent signed or thumb print and witnessed | X |
| | | |
| Exclusion | Any exclusion criterion | X |
| | Presence of any significant known systemic disorder | X |
| | History of congenital abdominal disorders, intussusception, abdominal surgery or any other congenital disorder | X |
| | Screening positive with hepatitis B antigen and/or hepatitis C antibodies | X |
| | Use of other experimental agents within 30 days prior or after vaccination | X |
| | Clinically significant abnormalities in screening hematology or serum chemistry | X |
| | History of febrile illness wihtin 48 hours prior to vaccinatin and fever at the time of immunization) | |
| | Prior receipt of any cholera or ETEC vaccine | X |
| | Prior receipt of a blood transfusion or blood products including immunoglobulins | X |
| | Current use of iron or zinc supplements in 7 days prior to vaccination, current use of antacids or immunosuppressive drugs | X |
| | Any condition which, in the opinion of the investigator, might jeopardize the safety of study participants | X |
| | Receipt of antimicrobial drugs for any reason within 14 days of vaccination | X |
| | History of diarrhea during the 7 days prior to vaccination | X |
| | Culture positive for ETEC, *Shigella, V. Cholerae, Salmonella* or Rotavirus within 7 days of vaccination | X |
| | Acute disease at the time of enrollment or 3 days prior to enrollment | X |
| | Known or suspected impairment of immunological function | X |
| | Participant's parents/guardians not able, available or willing to accept weekly follow-up by study staff | X |
| | History of chronic administration of immunosuppressant medications | X |
| | Any medical condition in the parents/infants that, in the judgment of the investigator, would interfere with the study | X |
| | Medically significant malnutrition | X |
| | | |
| Other | Other | X |

## TABLE 14.1.2(a):
## Analysis Populations by Treatment Group - Adults

| Analysis Populations | Reason Participants Excluded | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part A of the study.

## TABLE 14.1.2(b):
## Analysis Populations by Treatment Group - Toddlers (24 - 59 Months)

| Analysis Populations | Reason Participants Excluded | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part B of the study.

**TABLE 14.1.2(b): continued**
**Analysis Populations by Treatment Group - Toddlers (24 - 59 Months)**

| Analysis Populations | Reason Participants Excluded | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part B of the study.

**TABLE 14.1.2(c):**
**Analysis Populations by Treatment Group - Young Children (12 - 23 Months)**

| Analysis Populations | Reason Participants Excluded | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part C of the study.

**TABLE 14.1.2(c): continued**
**Analysis Populations by Treatment Group - Young Children (12 - 23 Months)**

| Analysis Populations | Reason Participants Excluded | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part C of the study.

## TABLE 14.1.2(d):
## Analysis Populations by Treatment Group - Infants (6 - 11 Months)

| Analysis Populations | Reason Participants Excluded | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part D of the study.

**TABLE 14.1.2(d): continued**
**Analysis Populations by Treatment Group - Infants (6 - 11 Months)**

| Analysis Populations | Reason Participants Excluded | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | % | n |
| Safety Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Safety Data Available | x | x.x | x | x.x | x | x.x | x | x.x |
| Full Analysis Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |
| Per Protocol Population | Any Reason | x | x.x | x | x.x | x | x.x | x | x.x |
| | Not Randomized/Not Vaccinated | x | x.x | x | x.x | x | x.x | x | x.x |
| | Did Not Receive Both Vaccinations | x | x.x | x | x.x | x | x.x | x | x.x |
| | Both Vaccinations were not Same Dose | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Pre-vaccination Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | No Valid Post Dose 2 Immunogenicity Assessment | x | x.x | x | x.x | x | x.x | x | x.x |
| | Major Protocol Violation | x | x.x | x | x.x | x | x.x | x | x.x |

N=Number of participants enrolled in Part D of the study.

## TABLE 14.1.3(a):
## Participant Disposition by Treatment Group - Adults

| Participant Disposition | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % |
| Screened | | | | | | | xx | -- |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N=Number of participants enrolled in Part A of the study.

[a]Refer to Listing 16.2.1 for reasons participants discontinued or terminated early.

[b]Refer to Listing 16.2.3 for reasons participants are excluded from the immunogenicity analysis.

## TABLE 14.1.3(b):
## Participant Disposition by Treatment Group - Toddlers (24 - 59 Months)

| Participant Disposition | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % | n | % |
| Screened | | | | | | | | | | |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

| Participant Disposition | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % | n | % |
| Screened | | | | | | | | | xx | --- |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N=Number of participants enrolled in Part B of the study.

[a]Refer to Listing 16.2.1 for reasons participants discontinued or terminated early.

[b]Refer to Listing 16.2.3 for reasons participants are excluded from the immunogenicity analysis.

## TABLE 14.1.3(c):
## Participant Disposition by Treatment Group - Young Children (12 - 23 Months)

| Participant Disposition | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % |
| Screened | | | | | | | | |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

| Participant Disposition | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % |
| Screened | | | | | | | xx | -- |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N=Number of participants enrolled in Part C of the study.

[a]Refer to Listing 16.2.1 for reasons participants discontinued or terminated early.

[b]Refer to Listing 16.2.3 for reasons participants are excluded from the immunogenicity analysis

## TABLE 14.1.3(d):
## Participant Disposition by Treatment Group - Infants (6 - 11 Months)

| Participant Disposition | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % | n | % |
| Screened | | | | | | | | | | |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

| Participant Disposition | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | n | n | % | n | % |
| Screened | | | | | | | xx | -- |
| Enrolled/Randomized | xx | 100.0 | xx | 100.0 | xx | 100.0 | xx | 100.0 |
| Received First Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Received Second Vaccination | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Visit 7 (Day 42) | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Completed Follow-up at 6 Months Post-Vac [a] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Full Analysis Population[b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Per Protocol population [b] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N=Number of participants enrolled in Part D of the study.

[a]Refer to Listing 16.2.1 for reasons participants discontinued or terminated early.

[b]Refer to Listing 16.2.3 for reasons participants are excluded from the immunogenicity analysis

**TABLE 14.1.4.1(a):**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Adults**

| Demographic Category | Characteristic | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.1(b):**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Toddlers (24 - 59 Months)**

| Demographic Category | Characteristic | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.1(b): continued**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Toddlers (24 - 59 Months)**

| Demographic Category | Characteristic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.1(c):**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Young Children (12 - 23 Months)**

| Demographic Category | Characteristic | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for Height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

**TABLE 14.1.4.1(c): Continued**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Young Children (12 - 23 Months)**

| Demographic Category | Characteristic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for Height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.1(d):**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Infants (6 - 11 Months)**

| Demographic Category | Characteristic | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.1(d): Continued**
**Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - Infants (6 - 11 Months)**

| Demographic Category | Characteristic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| Sex | Male | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Female | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Race | Black | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | White | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Asian | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Unknown | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for age malnutrition (underweight) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Heigtht for age malnutrition (stunting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| Weight for Height malnutrtion (wasting) | None | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Mild | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Moderate | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| | Severe | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |

N = Number of participants in the Safety population. n = Number of participants reporting the response.

**TABLE 14.1.4.2(a):**
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Adults**

| Variable | Statistic | Placebo (N=XX) | ETVAX Full Dose (N=XX) | ETVAX Full Dose + 10 µg dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|---|
| Age (years) | n | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x |
| | Maximum | x | x | x | x |
| Height (cm) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(b):**
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Toddlers (24 - 59 Months)**

| Variable | Statistic | Placebo (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | ETVAX Full Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|---|---|
| Age (months) | n | x | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x | x |
| | Maximum | x | x | x | x | x |
| Length (cm) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(b): Continued**
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Toddlers (24 - 59 Months)**

| Variable | Statistic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|---|---|
| Age (months) | n | x | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x | x |
| | Maximum | x | x | x | x | x |
| Length (cm) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(c):**
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Young Children (12 - 23 Months)**

| Variable | Statistic | Placebo (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|---|
| Age (months) | n | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x |
| | Maximum | x | x | x | x |
| Length (cm) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(c):** Continued

**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Young Children (12 - 23 Months)**

| Variable | Statistic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|---|
| Age (month) | n | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x |
| | Maximum | x | x | x | x |
| Length (cm) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(d):**
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Infants (6 - 11 Months)**

| Variable | Statistic | Placebo (N=XX) | ETVAX 1/8 Dose (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|---|---|
| Age (months) | n | x | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x | x |
| | Maximum | x | x | x | x | x |
| Length (cm) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.4.2(d):** Continued
**Summary of Continuous Demographic and Baseline Characteristics by Treatment Group - Infants (6 - 11 Months)**

| Variable | Statistic | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|---|
| Age (months) | n | x | x | x | x |
| | Mean | x.x | x.x | x.x | x.x |
| | Standard Deviation | x.xx | x.xx | x.xx | x.xx |
| | Median | x | x | x | x |
| | 25th Percentile | x.x | x.x | x.x | x.x |
| | 75th Percentile | x.x | x.x | x.x | x.x |
| | Minimum | x | x | x | x |
| | Maximum | x | x | x | x |
| Length (cm) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |
| Weight (kg) | n | x | x | x | x |
| | Mean | xx.xx | x.xx | x.xx | x.xx |
| | Standard Deviation | x.xxx | x.xxx | x.xxx | x.xxx |
| | Median | x.x | x.x | x.x | x.x |
| | 25th Percentile | x.xx | x.xx | x.xx | x.xx |
| | 75th Percentile | x.xx | x.xx | x.xx | x.xx |
| | Minimum | x.x | x.x | x.x | x.x |
| | Maximum | x.x | x.x | x.x | x.x |

N = Number of participants in the Safety population. n = Number of participants with a response.

**TABLE 14.1.5(a):**
**Summary of Participants with Pre-Existing Medical Conditions by MedDRA® System Organ Class and Treatment Group - Adults**

| MedDRA® System Organ Class | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

**TABLE 14.1.5(b):**
**Summary of Participants with Pre-Existing Medical Conditions by MedDRA® System Organ Class and Treatment Group - Toddlers (24 - 59 Months)**

| MedDRA® System Organ Class | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

| MedDRA® System Organ Class | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

**TABLE 14.1.5(c):**
**Summary of Participants with Pre-Existing Medical Conditions by MedDRA® System Organ Class and Treatment Group - Young Children (12 - 23 Months)**

| MedDRA® System Organ Class | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

| MedDRA® System Organ Class | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

**TABLE 14.1.5(d):**
**Summary of Participants with Pre-Existing Medical Conditions by MedDRA® System Organ Class and Treatment Group - Infants (6 - 11 Months)**

| MedDRA® System Organ Class | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

| MedDRA® System Organ Class | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % |
| Any SOC | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 1] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 2] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| [SOC 3] | xx | xx.x | xx | xx.x | xx | xx.x | xx | xx.x |
| .... | | | | | | | | |

N= Number of participants in the Safety population; n = Number of participants reporting medical history within the specified SOC. A participant is only counted once per SOC.

**TABLE 14.1.6(a):**
**Dates of First Vaccination by Treatment Group - Adults**

| Dates of Dosing | Placebo (N=XX) | ETVAX Full Dose (N=XX) | ETVAX Full Dose + 10 µg dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|
| | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

## TABLE 14.1.6(b):
## Dates of First Vaccination by Treatment Group - Toddlers (24 - 59 Months)

| Dates of Dosing | Placebo (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | ETVAX Full Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|---|
| | n | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

| Dates of Dosing | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|---|
| | n | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

## TABLE 14.1.6(c):
## Dates of First Vaccination by Treatment Group - Young Children (12 - 23 Months)

| Dates of Dosing | Placebo (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|
| | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

| Dates of Dosing | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|
| | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

## TABLE 14.1.6(d):
## Dates of First Vaccination by Treatment Group - Infants (6 - 11 Months)

| Dates of Dosing | Placebo (N=XX) | ETVAX 1/8 Dose (N=XX) | ETVAX 1/4 Dose (N=XX) | ETVAX 1/2 Dose (N=XX) | Combined ETVAX Alone (N=XX) |
|---|---|---|---|---|---|
| | n | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

| Dates of Dosing | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | Combined ETVAX + dmLT (N=XX) | All Participants (N=XX) |
|---|---|---|---|---|
| | n | n | n | n |
| Total (Entire period of enrollment) | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| DDMMMYYYY | xx | xx | xx | xx |
| [categorize based on length of enrollment period] | | | | |

Note: N = number of participants in the Safety population; n = Number of participants receiving vaccination.

**TABLE 14.2.1.1(a):**
**Antibody IgA Response (≥2 Fold-Rise) in Antibody Lymphocyte Secretion - Adults**
**Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| **Antigen** | **Treatment** | **n** | **%** | **95% CI[a]** | **n** | **%** | **95% CI[a]** | **n** | **%** | **95% CI[a]** |
| LTB | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a two-sided exact (Clopper-Pearson) binomial method.

**TABLE 14.2.1.1(b):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months) Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.1.1(b): Continued**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months) Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a two-sided exact (Clopper-Pearson) binomial method.

**TABLE 14.2.1.1(c):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.1.1(c): Continued**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a two-sided exact (Clopper-Pearson) binomial method.

**TABLE 14.2.1.1(d):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| LTB | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.1.1(d): Continued**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Antibody Response (≥2 Fold-Rise) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Baseline to Any Time Post Dose | | |
| Antigen | Treatment | n | % | 95% CI[a] | n | % | 95% CI[a] | n | % | 95% CI[a] |
| CS6 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a two-sided exact (Clopper-Pearson) binomial method.

**TABLE 14.2.1.1(e):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Adults**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.1.1(a)***.

**TABLE 14.2.1.1(f):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.1.1(b)***

**TABLE 14.2.1.1(g):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.1.1(c)***

**TABLE 14.2.1.1(h):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.1.1(d)***

**TABLE 14.2.1.2(a):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(a)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(b):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(b)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(c):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(c)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(d):**
**Antibody Response (≥2 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(d)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(e):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(e)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(f):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(f)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(g):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(g)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.2(h):**
**Antibody Response (≥4 Fold-Rise) by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.1(h)**, but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.3(a):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Adults**
**Full Analysis Population**

| Antigen | Comparison | P-value from Fisher's Exact Test | | | | | |
|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | Baseline to Post Dose 2 | | Baseline to Any Timepoint | |
| | | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold |
| LTB | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |
| CFA/I | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |
| CS3 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |
| CS6 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |
| CS5 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |
| 078 LPS | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | | | | |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | | | | |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.1.3(b):**
**Comparison of Antibody Response to LTB by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

| Comparison | P-value from Fisher's Exact Test | | | | | |
|---|---|---|---|---|---|---|
| | Baseline to Post Dose 1 | | Baseline to Post Dose 2 | | Baseline to Any Timepoint | |
| | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold |
| Comparing Different Doses of ETVAX without dmLT | | | | | | |
| ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| Comparing ETVAX without dmLT with ETVAX with DMLT | | | | | | |
| ETVAX 1/2 Dose vs ETVAX 1/2 Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| ETVAX 1/2 Dose vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| ETVAX 1/2 Dose vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| ETVAX 1/4 Dose vs ETVAX 1/2 Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| ETVAX 1/4 Dose vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| ETVAX 1/4 Dose vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | | | | |
| Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| Placebo vs ETVAX 1/2 Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| Placebo vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| Placebo vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| Comparing different doses of dmLT with ETVAX 1/2 Dose | | | | | | |
| 2.5 µg dmLT vs 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| 2.5 µg dmLT vs 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| 5 µg dmLT vs 10 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| Combined Treatment Comparisons | | | | | | |
| Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |
| Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | | | | |
| Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |

*Programming Note: Continue Table 14.2.2.1(b) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.1.3(c):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| Antigen | Comparison | P-value from Fisher's Exact Test | | | | | |
|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | Baseline to Post Dose 2 | | Baseline to Any Timepoint | |
| | | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| | Comparing Different Doses of ETVAX with dmLT | | | | | | |
| | ETVAX 1/2 Dose + 5 µg dmLT vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Comparing ETVAX without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/4 Dose vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/4 Dose vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| | Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/2 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/2 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Combined Treatment Comparisons | | | | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.2.1(c) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.1.3(d):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| Antigen | Comparison | P-value from Fisher's Exact Test | | | | | |
|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | Baseline to Post Dose 2 | | Baseline to Any Timepoint | |
| | | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold | ≥2-fold | ≥4-fold |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/4 Dose vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | | | | |
| | Comparing Different Doses of ETVAX with dmLT | | | | | | |
| | ETVAX 1/4 Dose + 5 µg dmLT vs ETVAX 1/4 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Comparing ETVAX without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/4 Dose vs ETVAX 1/4 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/4 Dose vs ETVAX 1/4 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/8 Dose vs ETVAX 1/4 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | ETVAX 1/8 Dose vs ETVAX 1/4 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| | Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/4 Dose + 5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs ETVAX 1/4 Dose + 2.5 µg dmLT | 0.xxxx | 0.xxxx | | | | |
| | Combined Treatment Comparisons | | | | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | | | | |
| | Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | | | | |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.2.1(d) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.1.3(e):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.2.1(a), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.3(f):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.2.1(b), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.3(g):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.2.1(c), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.1.3(h):**
**Comparison of Antibody Response by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.2.1(d), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.2.1(a):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Adults**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| LTB | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMT = Geometric mean titer; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a t-test.

**TABLE 14.2.2.1(b):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months) Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.2.1(b): continued**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months) Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMT = Geometric mean titer; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a t-test.

**TABLE 14.2.2.1(c):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.2.1(c): continued**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMT = Geometric mean titer; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a t-test.

**TABLE 14.2.2.1(d):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| LTB | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

**TABLE 14.2.2.1(d): continued**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
| Antigen | Treatment | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] | n | GMT | 95% CI of GMT[a] |
| CS6 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMT = Geometric mean titer; 95% CI = 95% confidence interval.
[a]95% CI is calculated using a t-test.

**TABLE 14.2.2.2(a):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.3.1(a), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.2.2(b):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.3.1(b), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.2.2(c):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.3.1(c), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.2.2(d):**
**Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.3.1(d), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.3.1(a):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Adults**
**Full Analysis Population**

| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
|---|---|---|---|---|---|---|---|
| | Comparisons Treatment 1 vs Treatment 2 | Ratio of GMT[a] | 95% CI[b] of GMT Ratio | P-value[c] | Ratio of GMT[a] | 95% CI[b] of GMT Ratio | P-value[c] |
| LTB | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| CFA/I | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| CS3 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| CS6 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| CS5 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| 078 LPS | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |

[a]Ratio of GMT = GMT for Treatment 1/ GMT for Treatment 2.

[b]The confidence intervals are constructed using a t distribution on the difference in the natural log transformed antibody titers, the mean difference and CIs will be back transformed to get the GMT ratio and 95% CI of the ratio.

[c]P-value is from a t-test.

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.3.1(b):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
|---|---|---|---|---|---|---|---|
| | **Comparisons Treatment 1 vs Treatment 2** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | | | | |
| | ETVAX Full Dose vs ETVAX 1/2 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | | | | |
| | ETVAX # mL + 10 µg dmLT vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX # mL + 10 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX Full Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX Full Dose vs ETVAX # mL + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |

[a]Ratio of GMT = GMT for Treatment 1/ GMT for Treatment 2.

[b]The confidence intervals are constructed using a t distribution on the difference in the natural log transformed antibody titers, the mean difference and CIs will be back transformed to get the GMT ratio and 95% CI of the ratio.

[c]P-value is from a t-test.

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

**TABLE 14.2.3.1(b): continued**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
|---|---|---|---|---|---|---|---|
| | **Comparisons Treatment 1 vs Treatment 2** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** |
| LTB | Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| | Placebo vs ETVAX Full Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX 1/2 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 10 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Combined Treatment Comparisons | | | | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |

[a]Ratio of GMT = GMT for Treatment 1/ GMT for Treatment 2.

[b]The confidence intervals are constructed using a t distribution on the difference in the natural log transformed antibody titers, the mean difference and CIs will be back transformed to get the GMT ratio and 95% CI of the ratio.

[c]P-value is from a t-test.

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.4.1(b) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.3.1(c):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
|---|---|---|---|---|---|---|---|
| | **Comparisons Treatment 1 vs Treatment 2** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** | **Ratio of GMT[a]** | **95% CI[b] of GMT Ratio** | **P-value[c]** |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | | | | |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| | Placebo vs ETVAX 1/2 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Combined Treatment Comparisons | | | | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |

[a]Ratio of GMT = GMT for Treatment 1/ GMT for Treatment 2.

[b]The confidence intervals are constructed using a t distribution on the difference in the natural log transformed antibody titers, the mean difference and CIs will be back transformed to get the GMT ratio and 95% CI of the ratio.

[c]P-value is from a t-test.

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.4.1(c) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.3.1(d):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | |
|---|---|---|---|---|---|---|---|
| | | Ratio of GMT[a] | 95% CI[b] of GMT Ratio | P-value[c] | Ratio of GMT[a] | 95% CI[b] of GMT Ratio | P-value[c] |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX 1/8 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX 1/8 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | | | | |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing ETVAX 1/8 Dose without dmLT with ETVAX with DMLT | | | | | | |
| | ETVAX 1/8 Dose vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | ETVAX 1/8 Dose vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Comparing Placebo to ETVAX with and without dmLT | | | | | | |
| | Placebo vs ETVAX 1/2 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX 1/8 Dose | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| LTB | Combined Treatment Comparisons | | | | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | x.xx | x.xx, x.xx | 0.xxxx | x.xx | x.xx, x.xx | 0.xxxx |

[a]Ratio of GMT = GMT for Treatment 1/ GMT for Treatment 2.
[b]The confidence intervals are constructed using a t distribution on the difference in the natural log transformed antibody titers, the mean difference and CIs will be back transformed to get the GMT ratio and 95% CI of the ratio.
[c]P-value is from a t-test.
* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.4.1(d) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.3.2(a):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.4.1(a), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.3.2(b):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.4.1(b), but use the Per Protocol population instead of the Full Analysis population.*

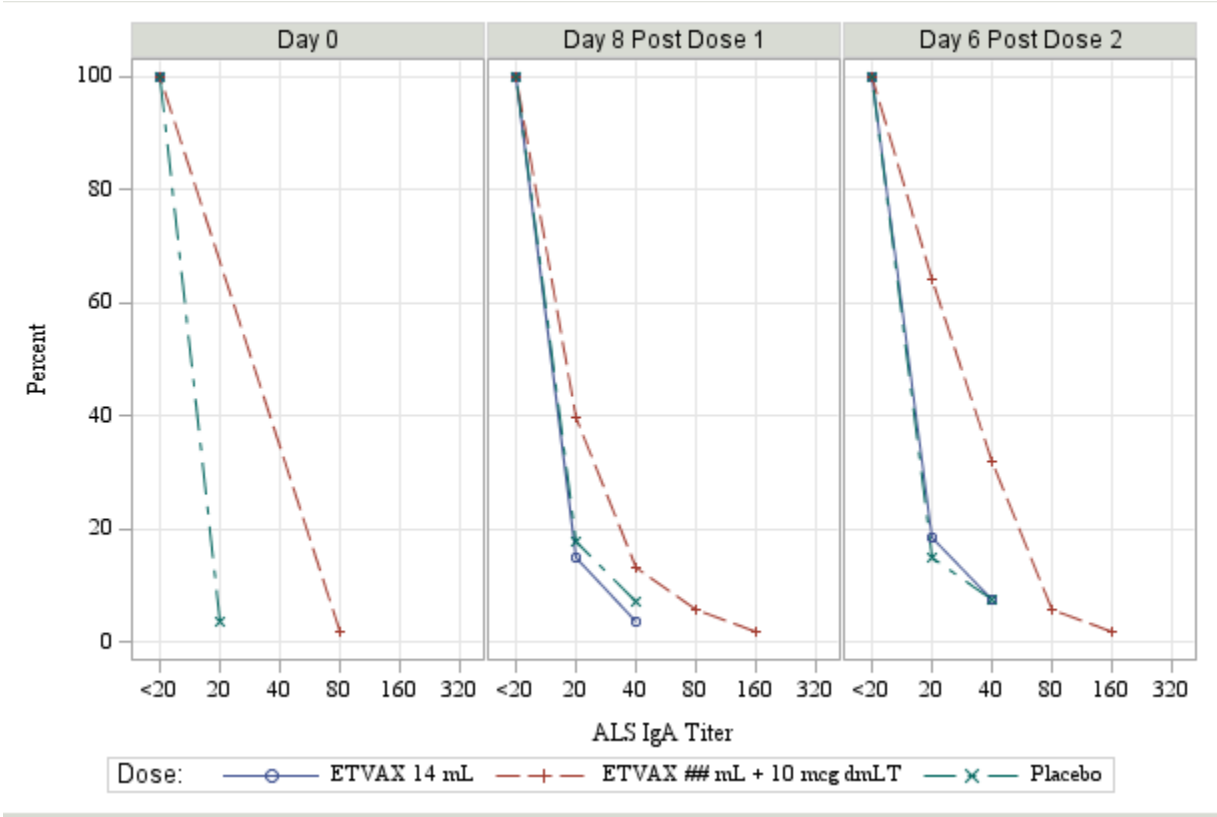
**TABLE 14.2.3.2(c):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.4.1(c), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.3.2(d):**
**Comparison of Geometric Mean Titer by Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

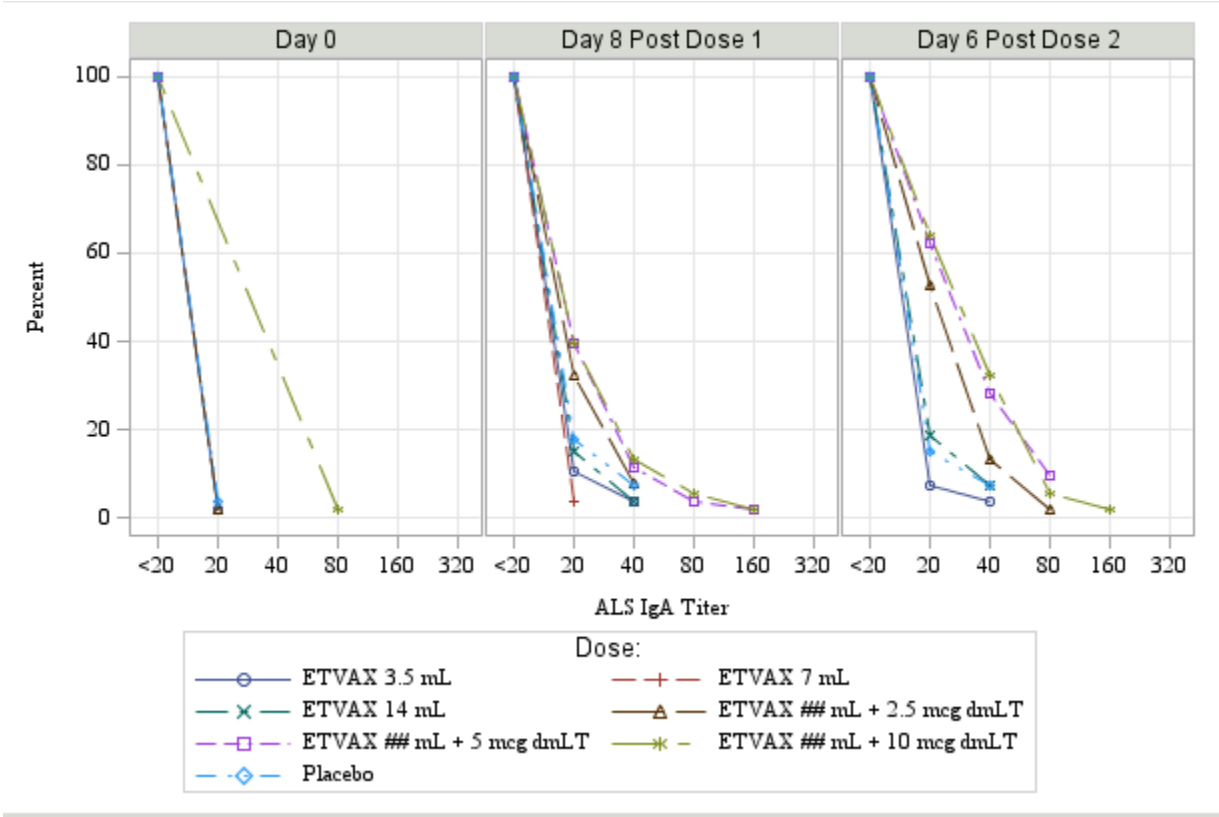
*Programming Note: Use the same Table shell as Table 14.2.4.1(d), but use the Per Protocol population instead of the Full Analysis population.*

**FIGURE 14.2.4.1a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Adults**
**Full Analysis Population**
**LTB Antigen**



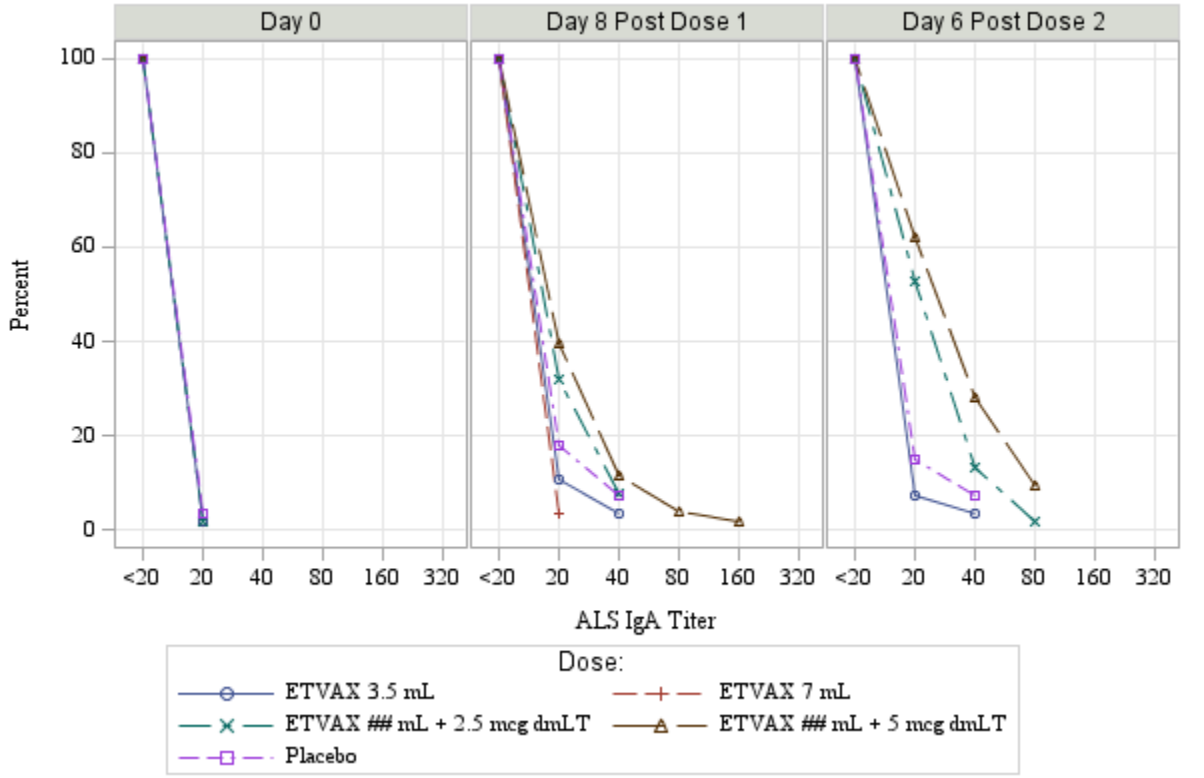

*Programming Note: Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS.*

**FIGURE 14.2.4.1b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Full Analysis Population**
**LTB Antigen**



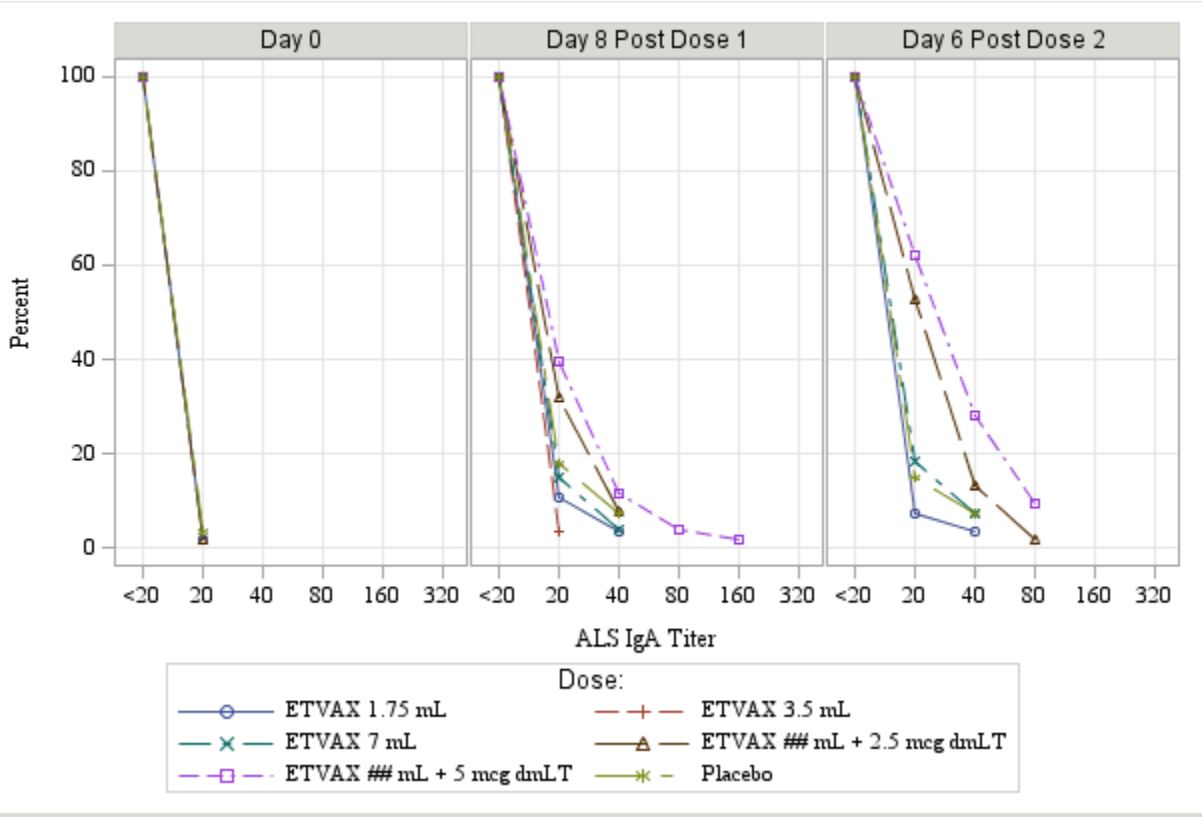

*Programming Note: Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS.*

**FIGURE 14.2.4.1c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Young Children (12 - 23 Months)**
**Full Analysis Population**
**LTB Antigen**




*Programming Note: Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS.*

**FIGURE 14.2.4.1d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Full Analysis Population**
**LTB Antigen**




*Programming Note: Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.4.2a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Adults**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as Figure 14.2.5.1a shell except change population from Full Analysis Population to Per Protocol Population. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.4.2b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as Figure 14.2.5.1b shell except change population from Full Analysis Population to Per Protocol Population. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.4.2c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion**
**- Young Children (12 - 23 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as Figure 14.2.5.1c shell except change population from Full Analysis Population to Per Protocol Population. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.4.2d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as Figure 14.2.5.1d shell except change population from Full Analysis Population to Per Protocol Population. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**TABLE 14.2.5.1(a):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Adults**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| LTB | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose + 10 µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMFR = Geometric mean fold rise; 95% CI = 95% confidence interval.
[a]Geometric Mean Fold-rise. [b]95% CI, calculated using a t-test.

**TABLE 14.2.5.1(b):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX Full Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 10µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMFR = Geometric mean fold rise; 95% CI = 95% confidence interval.

[a]Geometric Mean Fold-rise. [b]95% CI, calculated using a t-test.

**TABLE 14.2.5.1(c):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Young Children (12 - 23 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| LTB | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Post Dose 1 (Day 7) | | | Post Dose 2 (Day 19) | | | Post Dose 1 to Post Dose 2 | | |
| **Antigen** | **Treatment** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** | **n** | **GMFR[a]** | **95% CI of GMFR[b]** |
| CS6 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMFR = Geometric mean fold rise; 95% CI = 95% confidence interval.
[a]Geometric Mean Fold-rise. [b]95% CI, calculated using a t-test.

**TABLE 14.2.5.1(d):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Full Analysis Population**

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Post Dose 1 to Post Dose 2 | | |
| Antigen | Treatment | n | GMFR[a] | 95% CI of GMFR[b] | n | GMFR[a] | 95% CI of GMFR[b] | n | GMFR[a] | 95% CI of GMFR[b] |
| LTB | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CFA/I | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS3 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

| | | Visits | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Baseline to Post Dose 1 | | | Baseline to Post Dose 2 | | | Post Dose 1 to Post Dose 2 | | |
| Antigen | Treatment | n | GMFR[a] | 95% CI of GMFR[b] | n | GMFR[a] | 95% CI of GMFR[b] | n | GMFR[a] | 95% CI of GMFR[b] |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS6 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| CS5 | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| 078 LPS | ETVAX 1/8 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/4 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX 1/2 Dose (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX Alone (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 2.5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | ETVAX (highest safe dose) + 5µg dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Combined ETVAX + dmLT (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |
| | Placebo (N=xx) | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x | xx | xx.x | xx.x, xx.x |

N=Number of participants in the population; n = Number of participants with an antibody response; GMFR = Geometric mean fold rise; 95% CI = 95% confidence interval.
[a]Geometric Mean Fold-rise. [b]95% CI, calculated using a t-test.

**TABLE 14.2.5.2(a):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.6.1(a), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.5.2(b):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.6.1(b), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.5.2(c):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.6.1(c), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.5.2(d):**
**Geometric Mean Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.6.1(d), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.6.1(a):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Adults**
**Full Analysis Population**

| Antigen | Comparison | P-value from T-Test | | |
|---|---|---|---|---|
| | | Baseline to Post Dose 1 | Baseline to Post Dose 2 | Post Dose 1 to Post Dose 2 |
| LTB | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| CFA/I | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| CS3 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| CS6 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| CS5 | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| 078 LPS | ETVAX Full Dose vs ETVAX Full Dose + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose + 10 µg dmLT vs Placebo | 0.xxxx | 0.xxxx | 0.xxxx |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.6.1(b):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Full Analysis Population**

| Antigen | Comparison | P-value from t-test | | |
|---|---|---|---|---|
| | | Baseline to Post Dose 1 | Baseline to Post Dose 2 | Post Dose 1 to Post Dose 2 |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | |
| | ETVAX Full Dose vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | |
| | ETVAX # mL + 10 µg dmLT vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX # mL + 10 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX Full Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX Full Dose vs ETVAX # mL + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX Full Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |

| Antigen | Comparison | P-value from t-test | | |
|---|---|---|---|---|
| | | Baseline to Post Dose 1 | Baseline to Post Dose 2 | Post Dose 1 to Post Dose 2 |
| LTB | Comparing Placebo to ETVAX with and without dmLT | | | |
| | Placebo vs ETVAX Full Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 10 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Combined Treatment Comparisons | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.2.1(b) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.6.1(c):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Young Children (12 - 23 Months)**
**Full Analysis Population**

| Antigen | Comparison | P-value from t-test | | |
|---|---|---|---|---|
| | | Baseline to Post Dose 1 | Baseline to Post Dose 2 | Post Dose 1 to Post Dose 2 |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing Placebo to ETVAX with and without dmLT | | | |
| | Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Combined Treatment Comparisons | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.7.1(c) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.6.1(d):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Full Analysis Population**

| Antigen | Comparison | P-value from t-test | | |
|---|---|---|---|---|
| | | Baseline to Post Dose 1 | Baseline to Post Dose 2 | Baseline to Any Timepoint |
| LTB | Comparing Different Doses of ETVAX without dmLT | | | |
| | ETVAX 1/2 Dose vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing Different Doses of ETVAX with dmLT | | | |
| | ETVAX # mL + 5 µg dmLT vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/2 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/2 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/2 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/4 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/4 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/4 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing ETVAX 1/8 Dose without dmLT with ETVAX with DMLT | | | |
| | ETVAX 1/8 Dose vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | ETVAX 1/8 Dose vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Comparing Placebo to ETVAX with and without dmLT | | | |
| | Placebo vs ETVAX 1/2 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX 1/4 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX 1/8 Dose | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs ETVAX # mL + 2.5 µg dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| LTB | Combined Treatment Comparisons | | | |
| | Combined ETVAX without dmLT vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX without dmLT | 0.xxxx | 0.xxxx | 0.xxxx |
| | Placebo vs Combined ETVAX with dmLT | 0.xxxx | 0.xxxx | 0.xxxx |

* Using Holm's-Bonferroni adjustment within each antigen, the p-value is statistically significant.

*Programming Note: Continue Table 14.2.7.1(d) for each antigen in the following order: CFA/I, CS3, CS6, CS5, and 078 LPT. For each antigen, the Holm's-Bonferroni correction will be performed. If a p-value is statistically significant after the adjustment, a "*" will be placed next to the p-value.*

**TABLE 14.2.6.2(a):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Adults**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.7.1(a), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.6.2(b):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Toddlers (24 - 59 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.7.1(b), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.6.2(c):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Young Children (12 - 23 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.7.1(c), but use the Per Protocol population instead of the Full Analysis population.*

**TABLE 14.2.6.2(d):**
**Comparison of Geometric Fold Rise in IgA Titer by Antibody Lymphocyte Secretion - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as Table 14.2.7.1(d), but use the Per Protocol population instead of the Full Analysis population.*

# Fecal Secretion

**TABLE 14.2.7.1(a):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.7.1(b):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.7.1(c):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.7.1(d):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.7.1(e):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.7.1(f):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.7.1(g):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.7.1(h):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as Table 14.2.1.1(a) to (h), change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28".*

**TABLE 14.2.7.2(a):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.7.2(b):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.7.2(c):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.7.2(d):**
**Antibody Response (≥ 2 Fold) by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

**TABLE 14.2.7.2(e):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.7.2(f):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.7.2(g):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.7.2(h):**
**Antibody Response (≥ 4 Fold) by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as Table 14.2.1.2(a) to (h), change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28".*

**TABLE 14.2.7.3(a):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.7.3(b):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.7.3(c):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.7.3(d):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.7.3(e):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.7.3(f):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.7.3(g):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.7.3(h):**
**Comparison of Antibody Responses Measured by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as **Table 14.2.2.1(a) to (h)**, change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Day 28"*

**TABLE 14.2.8.1(a):**
**Geometric Mean Titer by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.8.1(b):**
**Geometric Mean Titer by Fecal Secretion IgA - Toddlers (23 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.8.1(c):**
**Geometric Mean Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.8.1(d):**
**Geometric Mean Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.8.2(a):**
**Geometric Mean Titer by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.8.2(b):**
**Geometric Mean Titer by Fecal Secretion IgA - Toddlers (23 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.8.2(c):**
**Geometric Mean Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.8.2(d):**
**Geometric Mean Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as **Table 14.2.2.1(a) to 14.2.2.2 (d)**, add another set of columns for "Day 28"*

**TABLE 14.2.9.1(a):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.9.1(b):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.9.1(c):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.9.1(d):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as **Table 14.2.3.1(a) to (d)**, add another set of columns for "Post Dose 2 (Day 28)"*

**TABLE 14.2.9.2(a):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.9.2(b):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.9.2(c):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.9.2(d):**
**Comparison of Geometric Mean Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as **Table 14.2.3.2(a) to (d)** but use Per Protocol population instead of Full Analysis population, add another set of columns for " Day 28"*

**FIGURE 14.2.10.1a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Adults**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.10.1b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Toddlers (24 - 59 Months)**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.10.1c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Young Children (12 - 23 Months)**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.10.1d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Infants (6 - 11 Months)**
**Full Analysis Population**
**LTB Antigen**

*Programming Note: Use same format as* ***Figures 14.2.4.1(a) to (d)*** *shell except add another timepoint - Day 28. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.10.2a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Adults**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.10.2b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Toddlers (24 - 59 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.10.2c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Young Children (12 - 23 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.10.2d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Fecal Secretion - Infants (6 - 11 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as **Figures 14.2.4.2(a) to (d)** shell except change population from Full Analysis Population to Per Protocol Population and add another timepoint - Day 28. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**TABLE 14.2.11.1(a):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.11.1(b):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.11.1(c):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.11.1(d):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as **Table 14.2.5.1(a) to (d)**, change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28".*

**TABLE 14.2.11.2(a):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.11.2(b):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.11.2(c):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.11.2(d):**
**Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as **Table 14.2.5.2(a) to (d)**, but use the Per Protocol population instead of the Full Analysis Population, change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28".*

**TABLE 14.2.12.1(a):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.12.1(b):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.12.1(c):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.12.1(d):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as **Table 14.2.6.1(a) to (d)**, change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28"*

**TABLE 14.2.12.2(a):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.12.2(b):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.12.2(c):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.12.2(d):**
**Comparison of Geometric Mean Fold Rise in Titer by Fecal Secretion IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shells as **Table 14.2.6.2(a) to (d)** but use Per Protocol population instead of Full Analysis population, change the "Baseline to Post Dose 2" to "Baseline to Post Dose 2 (Day 19)" and add "Baseline to Day 28"*

# Plasma IgA

**TABLE 14.2.13.1(a):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.13.1(b):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.13.1(c):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.13.1(d):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.13.1(e):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.13.1(f):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.13.1(g):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.13.1(h):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as **Table 14.2.1.1(a) to (h)**.*

**TABLE 14.2.13.2(a):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.13.2(b):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.13.2(c):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.13.2(d):**
**Antibody Response (≥ 2 Fold) by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

**TABLE 14.2.13.2(e):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.13.2(f):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.13.2(g):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.13.2(h):**
**Antibody Response (≥ 4 Fold) by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.2(a) to (h)**.*

**TABLE 14.2.13.3(a):**
**Comparison of Antibody Response by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.13.3(b):**
**Comparison of Antibody Response by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.13.3(c):**
**Comparison of Antibody Response by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.13.3(d):**
**Comparison of Antibody Response by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.13.3(e):**
**Comparison of Antibody Response by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.13.3(f):**
**Comparison of Antibody Response by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.13.3(g):**
**Comparison of Antibody Response by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.13.3(h):**
**Comparison of Antibody Response by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.3(a) to (h)**.*

**TABLE 14.2.14.1(a):**
**Geometric Mean Titer by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.14.1(b):**
**Geometric Mean Titer by Plasma IgA - Toddlers (23 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.14.1(c):**
**Geometric Mean Titer by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.14.1(d):**
**Geometric Mean Titer by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.2.1(a) to (d).***

**TABLE 14.2.14.2(a):**
**Geometric Mean Titer by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.14.2(b):**
**Geometric Mean Titer by Plasma IgA - Toddlers (23 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.14.2(c):**
**Geometric Mean Titer by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.14.2(d):**
**Geometric Mean Titer by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.2.2(a) to (d)****.*

**TABLE 14.2.15.1(a):**
**Comparison of Geometric Mean Titer by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.15.1(b):**
**Comparison of Geometric Mean Titer by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.15.1(c):**
**Comparison of Geometric Mean Titer by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.15.1(d):**
**Comparison of Geometric Mean Titer by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.3.1(a) to (d).***

**TABLE 14.2.15.2(a):**
**Comparison of Geometric Mean Titer by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.15.2(b):**
**Comparison of Geometric Mean Titer by Plasma IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.15.2(c):**
**Comparison of Geometric Mean Titer by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.15.2(d):**
**Comparison of Geometric Mean Titer by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.3.2(a) to (d)****.*

**FIGURE 14.2.16.1a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Adults**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.16.1b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Toddlers (24 - 59 Months)**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.16.1c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Young Children (12 - 23 Months**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.16.1d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Infants (6 - 11 Months)**
**Full Analysis Population**
**LTB Antigen**

*Programming Note: Use same format as* ***Figure 14.2.4.1(a) to (d).*** *Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**FIGURE 14.2.16.2a:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Adults**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.16.2b:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Toddlers (24 - 59 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.16.2c:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Young Children (12 - 23 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.16.2d:**
**Reverse Cumulative Distribution Curves of IgA Responses in Plasma - Infants (6 - 11 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as **Figure 14.2.4.2(a) to (d)**. Continue for each antigen analyzed: CFA/I, CS3, CS6, CS5, 078 LPS*

**TABLE 14.2.17.1(a):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.17.1(b):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.17.1(c):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.17.1(d):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.5.1(a) to (d).***

**TABLE 14.2.17.2(a):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.17.2(b):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.17.2(c):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.17.2(d):**
**Geometric Mean Fold Rise in Titer, by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.5.2(a) to (d),***.

**TABLE 14.2.18.1(a):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Adults**
**Full Analysis Population**

**TABLE 14.2.18.1(b):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.18.1(c):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.18.1(d):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.6.1(a) to (d)***

**TABLE 14.2.18.2(a):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Adults**
**Per Protocol Population**

**TABLE 14.2.18.2(b):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.18.2(c):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.18.2(d):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgA - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as* ***Table 14.2.6.2(a) to (d)***.

# Plasma IgG

**TABLE 14.2.19.1(a):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.19.1(b):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.19.1(c):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.19.1(d):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.19.1(e):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.19.1(f):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.19.1(g):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.19.1(h):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shells as **Table 14.2.1.1(a) to (h)**. Only include LTB and 078 LPS.*

**TABLE 14.2.19.2(a):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.19.2(b):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.19.2(c):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.19.2(d):**
**Antibody Response (≥ 2 Fold) by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

**TABLE 14.2.19.2(e):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.19.2(f):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.19.2(g):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.19.2(h):**
**Antibody Response (≥ 4 Fold) by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.2(a) to (h)**. Only include LTB and 078 LPS.*

**TABLE 14.2.19.3(a):**
**Comparison of Antibody Response by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.19.3(b):**
**Comparison of Antibody Response by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.19.3(c):**
**Comparison of Antibody Response by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.19.3(d):**
**Comparison of Antibody Response by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

**TABLE 14.2.19.3(e):**
**Comparison of Antibody Response by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.19.3(f):**
**Comparison of Antibody Response by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.19.3(g):**
**Comparison of Antibody Response by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.19.3(h):**
**Comparison of Antibody Response by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.1.3(a) to (h)**. Only include LTB and 078 LPS.*

**TABLE 14.2.20.1(a):**
**Geometric Mean Titer by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.20.1(b):**
**Geometric Mean Titer by Plasma IgG - Toddlers (23 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.20.1(c):**
**Geometric Mean Titer by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.20.1(d):**
**Geometric Mean Titer by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.2.1(a) to (d).** Only include LTB and 078 LPS.*

**TABLE 14.2.20.2(a):**
**Geometric Mean Titer by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.20.2(b):**
**Geometric Mean Titer by Plasma IgG - Toddlers (23 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.20.2(c):**
**Geometric Mean Titer by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.20.2(d):**
**Geometric Mean Titer by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.2.2(a) to (d)** but use the Per Protocol popuation instead of the Full Analysis population. Only include LTB and 078 LPS.*

**TABLE 14.2.21.1(a):**
**Comparison of Geometric Mean Titer by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.21.1(b):**
**Comparison of Geometric Mean Titer by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.21.1(c):**
**Comparison of Geometric Mean Titer by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.21.1(d):**
**Comparison of Geometric Mean Titer by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.3.1(a) to (d).** Only include LTB and 078 LPS.*

**TABLE 14.2.21.2(a):**
**Comparison of Geometric Mean Titer by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.21.2(b):**
**Comparison of Geometric Mean Titer by Plasma IgG - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.21.2(c):**
**Comparison of Geometric Mean Titer by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.21.2(d):**
**Comparison of Geometric Mean Titer by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.3.2(a) to (d)** but use Per Protocol population instead of Full Analysis population. Only include LTB and 078 LPS.*

**FIGURE 14.2.22.1a:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Adults**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.22.1b:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Toddlers (24 - 59 Months)**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.22.1c:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Young Children (12 - 23 Months**
**Full Analysis Population**
**LTB Antigen**

**FIGURE 14.2.22.1d:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Infants (6 - 11 Months)**
**Full Analysis Population**
**LTB Antigen**

*Programming Note: Use same format as* ***Figure 14.2.4.1(a) to (d).*** *Continue for 078 LPS*

**FIGURE 14.2.22.2a:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Adults**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.22.2b:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Toddlers (24 - 59 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.22.2c:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Young Children (12 - 23 Months)**
**Per Protocol Population**
**LTB Antigen**

**FIGURE 14.2.22.2d:**
**Reverse Cumulative Distribution Curves of IgG Responses in Plasma - Infants (6 - 11 Months)**
**Per Protocol Population**
**LTB Antigen**

*Programming Note: Use same format as* ***Figure 14.2.4.2(a) to (d)****. Continue for 078 LPS*

**TABLE 14.2.23.1(a):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.23.1(b):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.23.1(c):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.23.1(d):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.5.1(a) to (d).** Only include LTB and 078 LPS.*

**TABLE 14.2.23.2(a):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.23.2(b):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.23.2(c):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.23.2(d):**
**Geometric Mean Fold Rise in Titer, by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.5.2(a) to (d)**. Only include LTB and 078 LPS.*

**TABLE 14.2.24.1(a):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Adults**
**Full Analysis Population**

**TABLE 14.2.24.1(b):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Toddlers (24 - 59 Months)**
**Full Analysis Population**

**TABLE 14.2.24.1(c):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Young Children (12 - 23 Months)**
**Full Analysis Population**

**TABLE 14.2.24.1(d):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Infants (6 - 11 Months)**
**Full Analysis Population**

*Programming Note: Use the same Table shell as **Table 14.2.6.1(a) to (d)** Only include LTB and 078 LPS.*

**TABLE 14.2.24.2(a):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Adults**
**Per Protocol Population**

**TABLE 14.2.24.2(b):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Toddlers (24 - 59 Months)**
**Per Protocol Population**

**TABLE 14.2.24.2(c):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Young Children (12 - 23 Months)**
**Per Protocol Population**

**TABLE 14.2.24.2(d):**
**Comparison of Geometric Mean Fold Rise in Titer, by Plasma IgG - Infants (6 - 11 Months)**
**Per Protocol Population**

*Programming Note: Use the same Table shell as **Table 14.2.6.2(a) to (d)**. Only include LTB and 078 LPS.*

**TABLE 14.3.1.1(a):**
**Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Treatment Group - Adults**

| Symptom | Placebo (N=XX) | | | ETVAX Full Dose (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | |
| Nausea | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | |
| Abdominal pain/stomach ache | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | |

N = number of participants in the Safety population.

**TABLE 14.3.1.1(b):**
**Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Treatment Group - Toddlers (24 - 59 Months)**

| Symptom | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | ETVAX Full Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | | | | |
| Abdominal pain/stomach ache | | | | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | | | | |

N = number of participants in the Safety population.

| Symptom | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | | | | |
| Abdominal pain/stomach ache | | | | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | | | | |

N = Number of participants in the Safety population.

**TABLE 14.3.1.1(c):**
**Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Treatment Group - Young Children (12 - 23 Months)**

| Symptom | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | |

N = number of participants in the Safety population.

| Symptom | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | |

N = number of participants in the Safety population.

**TABLE 14.3.1.1(d):**
**Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Treatment Group - Infants (6 - 11 Months)**

| Symptom | Placebo (N=XX) | | | ETVAX 1/8 Dose (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | | | | |

N = number of participants in the Safety population.

| Symptom | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | All Participants (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Elevated oral temperature | | | | | | | | | | | | |
| Vomiting | | | | | | | | | | | | |
| Loose stools | | | | | | | | | | | | |
| Diarrhea | | | | | | | | | | | | |
| Acute systemic allergic reaction | | | | | | | | | | | | |
| **Any Symptom** | | | | | | | | | | | | |

N = number of participants in the Safety population.

**TABLE 14.3.1.2(a):**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Adults**

| Symptom | Severity | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Nausea | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Vomiting | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Loose stools | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |

**TABLE 14.3.1.2(a): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Adults**

| Symptom | Severity | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| Diarrhea | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Abdominal pain/stomach ache | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.2(b):**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Toddlers (24 - 59 Months)**

| Symptom | Severity | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Abdominal pain/stomach ache | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.2(b): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Toddlers (24 - 59 Months)**

| Symptom | Severity | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Abdominal pain/stomach ache | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |

**TABLE 14.3.1.2(c):**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Young Children (12 - 23 Months)**

| Symptom | Severity | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Vomiting | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Loose stools | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Diarrhea | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.2(c): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Young Children (12 - 23 Months)**

| Symptom | Severity | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Vomiting | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Loose stools | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Diarrhea | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.2(d):**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Infants (6 - 11 Months)**

| Symptom | Severity | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | | | |
| | Mild | | | | | | | | | | |
| | Moderate | | | | | | | | | | |
| | Severe | | | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.2(d): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Symptom, Maximum Severity and Treatment Group - Infants (6 - 11 Months)**

| Symptom | Severity | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % |
| **Any Symptom** | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Vomiting | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Loose stools | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Diarrhea | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |
| Acute systemic allergic reaction | None | | | | | | | | |
| | Mild | | | | | | | | |
| | Moderate | | | | | | | | |
| | Severe | | | | | | | | |

N = Number of participants in the Safety population; Severity is based off of the maximum severity reported post vaccination.

**TABLE 14.3.1.3(a):**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Vaccination, Day Post Vaccination and Treatment Group - Adults**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| **Any Symptom** | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Nausea | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

**TABLE 14.3.1.3(a): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Day Post Vaccination and Treatment Group - Adults**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Diarrhea | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Abdominal pain/stomach ache | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Acute allergic systemic reaction | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

N = Number of participants in the Safety Population. Severity is the maximum severity reported for each participant for each day.

*Continue for each vaccination(Vaccination 1, Vaccination 2) and treatment: ETVAX Full Dose, ETVAX Full Dose + 10 µg dmLT, Placbo*

**TABLE 14.3.1.3(b):**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Vaccination, Day Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| **Any Symptom** | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

**TABLE 14.3.1.3(b): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Day Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Abdominal pain/stomach ache | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Acute allergic systemic reaction | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

N = Number of participants in the Safety Population. Severity is the maximum severity reported for each participant for each day.

*Continue for each vaccination (Vaccination 1, Vaccination 2) and treatment: ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX Full Dose, Combined ETVAX alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT, Combined ETVAX (highest safe dose) + dmLT, Placebo*

**TABLE 14.3.1.3(c):**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Vaccination, Day Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| **Any Symptom** | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

**TABLE 14.3.1.3(c): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Day Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Symptom | Severity | Pre-Trt (N=X) | | Post-Trt (N=X) | | Day 0 (N=X) | | Day 1 (N=X) | | Day 2 (N=X) | | Day 3 (N=X) | | Day 4 (N=X) | | Day 5 (N=X) | | Day 6 (N=X) | | Day 7 (N=X) | |
| | | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Acute allergic systemic reaction | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

N = Number of participants in the Safety Population. Severity is the maximum severity reported for each participant for each day.

*Continue for each vaccination (Vaccination1, Vaccination 2) and treatment: ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX (highest safe dose) + dmLT, Placebo*

**TABLE 14.3.1.3(d):**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Vaccination, Day Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| **Any Symptom** | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Elevated oral temperature | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Vomiting | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Loose stools | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |
| Diarrhea | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

**TABLE 14.3.1.3(d): continued**
**Number and Percentage of Participants Experiencing Solicited Events by Severity, Day Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

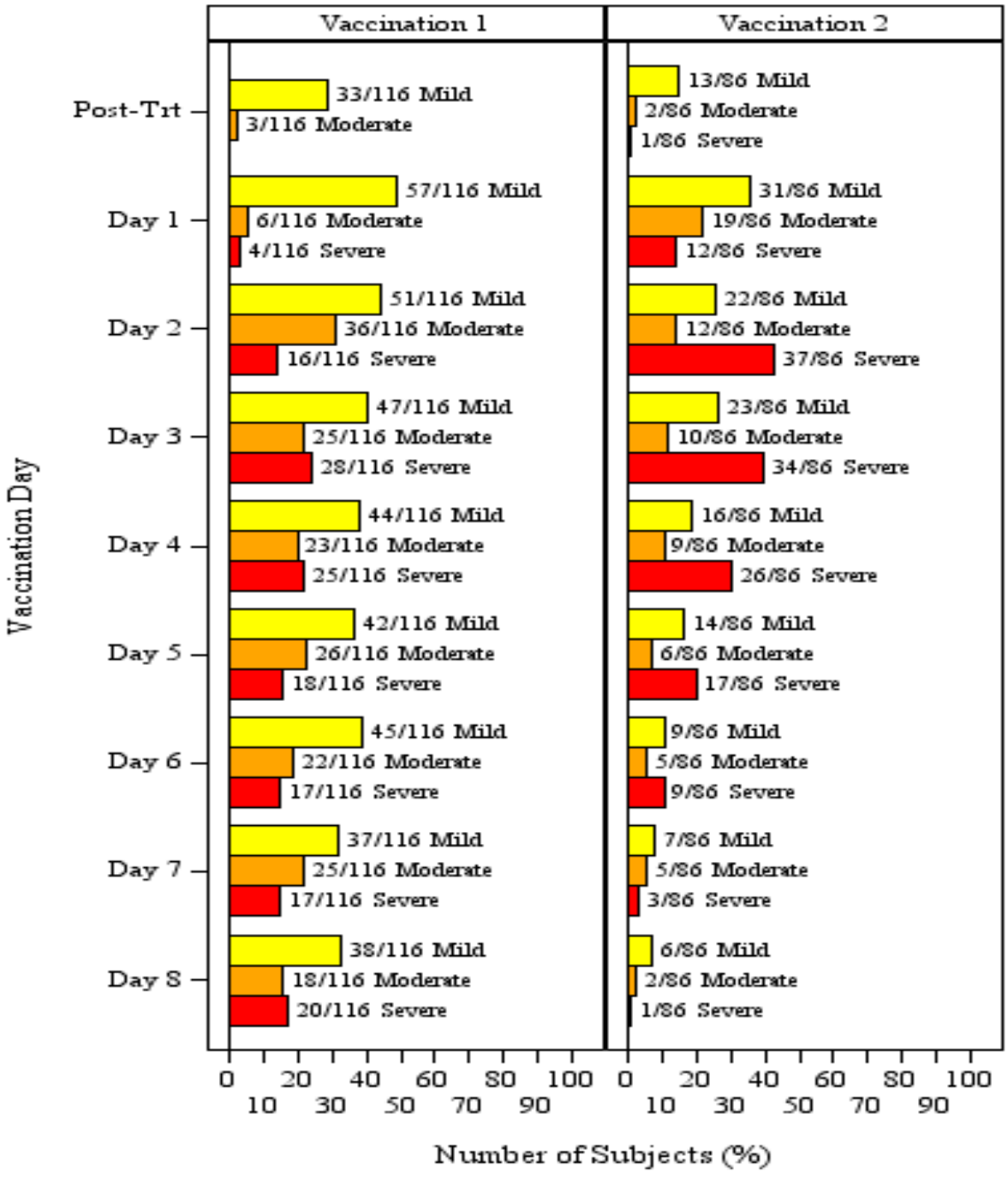
| Vaccination 1, All Participants (N=XX) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Symptom** | **Severity** | **Pre-Trt (N=X)** | | **Post-Trt (N=X)** | | **Day 0 (N=X)** | | **Day 1 (N=X)** | | **Day 2 (N=X)** | | **Day 3 (N=X)** | | **Day 4 (N=X)** | | **Day 5 (N=X)** | | **Day 6 (N=X)** | | **Day 7 (N=X)** | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Acute allergic systemic reaction | None | | | | | | | | | | | | | | | | | | | | |
| | Mild | | | | | | | | | | | | | | | | | | | | |
| | Moderate | | | | | | | | | | | | | | | | | | | | |
| | Severe | | | | | | | | | | | | | | | | | | | | |
| | Not Reported | | | | | | | | | | | | | | | | | | | | |

N = Number of participants in the Safety Population. Severity is the maximum severity reported for each participant for each day.

*Continue for each vaccination (Vaccination 1, Vaccination 2) and treatment: ETVAX 1/8 Dose, ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX (highest safe dose) + dmLT, Placebo*

**FIGURE 14.3.1.4a:**
**Maximum Severity of Solicited Events per Participant by Days Post Vaccination and Treatment Group - Adults**

**ETVAX Full Dose (N=XX)**




**Repeat for ETVAX Full Dose + 10 µg dmLT and Placebo.**

**FIGURE 14.3.1.4b:**
**Maximum Severity of Solicited Events per Participant**
**by Days Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.4a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

**FIGURE 14.3.1.4c:**
**Maximum Severity of Solicited Events per Participant**
**by Days Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.4a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.4d:**
**Maximum Severity of Solicited Events per Participant**
**by Days Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.4a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**TABLE 14.3.1.5a:**
**Comparison of the Proportion of Participants Experiencing Solicited Events by Treatment Group - Adults**

| Symptom | Placebo (N=XX) | | ETVAX Full Dose (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Nausea | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Abdominal pain/stomach ache | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

N = Number of participants in the Safety population; n = Number of participants with a symptom reported post-vaccination.
[a] P-value is from a Fisher's exact test, testing the treatment vs placebo.

**TABLE 14.3.1.5b:**
**Comparison of the Proportion of Participants Experiencing Solicited Events by Treatment Group - Toddlers (24 - 59 Months)**

| Symptom | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | ETVAX Full Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Abdominal pain/stomach ache | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

| Symptom | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 10 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Abdominal pain/stomach ache | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

N = Number of participants in the Safety population; n = Number of participants with a symptom reported post-vaccination.
[a] P-value is from a Fisher's exact test, testing the treatment vs placebo.

**TABLE 14.3.1.5c:**
**Comparison of the Proportion of Participants Experiencing Solicited Events by Treatment Group - Young Children (12 - 23 Months)**

| Symptom | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

| Symptom | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

N = Number of participants in the Safety population; n = Number of participants with a symptom reported post-vaccination.
[a] P-value is from a Fisher's exact test, testing the treatment vs placebo.

**TABLE 14.3.1.5d:**
**Comparison of the Proportion of Participants Experiencing Solicited Events by Treatment Group - Infants (6 - 11 Months)**

| | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Symptom | n | % | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

| | Combined ETVAX Alone (N=XX) | | | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Symptom | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] | n | % | P-value[a] |
| Any Symptom | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Elevated Oral Temperature | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Vomiting | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Loose stools | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Diarrhea | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |
| Acute systemic allergic reaction | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx | xx | xx.x | 0.xxx |

N = Number of participants in the Safety population; n = Number of participants with a symptom reported post-vaccination.
[a] P-value is from a Fisher's exact test, testing the treatment vs placebo.

**TABLE 14.3.1.6.1:**
**Univariate and Adjusted Odds of Vomiting after any ETVAX Dose (Day 0) Among Vaccinated Children 6 to 59 Months of Age**

| | | | Logistic Regression: OR (95% CI) | |
|---|---|---|---|---|
| Variable | Vomited[a] | No vomiting | Univariate | Adjusted |
| **Sex** | | | | |
| Female | n (%)[b] | n | OR (95% CI) | OR (95% CI) |
| Male | n (%) | n | 1 | 1 |
| | | | | |
| **Age (months)** | | | | |
| 6 to 11 | | | | |
| 12 to 23 | | | | |
| 24 to 59 | | | 1 | 1 |
| | | | | |
| **dmLT (mcg)** | | | | |
| 0 | | | | |
| 2.5 | | | | |
| 5.0 | | | | |
| 10.0 | | | 1 | 1 |
| | | | | |
| **Dose**[c] | | | | |
| ⅛ | | | | |
| ¼ | | | | |
| ½ | | | 1 | 1 |

[a]Mild or greater vomiting after first, second, or both doses on day 0.

[b]n (percent of row total)

[c]Exclude full dose recipients (n=5) from analysis.

**TABLE 14.3.1.6.2:**
**Univariate and Adjusted Odds of Vomiting after any ETVAX Dose (Day 0) Among All Children 6 to 59 Months of Age**

| | | | Logistic Regression | |
|---|---|---|---|---|
| Variable | Vomited[a] | No vomiting | Univariate | Adjusted |
| **Sex** | | | | |
| Female | n (%)[b] | n | OR (95% CI) | OR (95% CI) |
| Male | n (%) | n | 1 | 1 |
| | | | | |
| **Age (months)** | | | | |
| 6 to 11 | | | | |
| 12 to 23 | | | | |
| 24 to 59 | | | 1 | 1 |
| | | | | |
| **Dose**[c] | | | | |
| ETVAX | | | | |
| Placebo | | | | |

[a]Mild or greater vomiting after first, second, or both doses on day 0.

[b]n (percent of row total)

[c]Exclude full dose recipients (n=5) from analysis.

**TABLE 14.3.1.7a:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA® System Organ Class and Preferred Term, and Treatment Group - Adults**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo (N=XX) | | | ETVAX Full Dose (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | | Combined Vaccine (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |

N= Number of participants in the Safety Population. A participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.7b:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA® System Organ Class and Preferred Term, and Treatment Group - Toddlers (24 - 59 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | ETVAX Full Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |

| MedDRA® System Organ Class | MedDRA® Preferred Term | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | ETVAX Full Dose + 10 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | Combined Vaccine (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |

N= Number of participants in the Safety Population. A participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.7c:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA® System Organ Class and Preferred Term, and Treatment Group - Young Children (12 - 23 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |

| MedDRA® System Organ Class | MedDRA® Preferred Term | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | Combined Vaccine (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |

N= Number of participants in the Safety Population. A participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.7d:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA® System Organ Class and Preferred Term, and Treatment Group - Infants (6 - 11 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo (N=XX) | | | ETVAX 1/8 Dose (N=XX) | | | ETVAX 1/4 Dose (N=XX) | | | ETVAX 1/2 Dose (N=XX) | | | Combined ETVAX Alone (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | |

| MedDRA® System Organ Class | MedDRA® Preferred Term | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | | Combined ETVAX + dmLT (N=XX) | | | Combined Vaccine (N=XX) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) | n | % | (95% CI) |
| Any SOC | Any PT | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |

N= Number of participants in the Safety Population. A participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.8.1a:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity, Relationship and Treatment Group - Adults**

| ETVAX Full Dose (N=XX) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MedDRA® System Organ Class | MedDRA® Preferred Term | Any Incidence | | Severity[a] | | | | | | Relationship to Vaccination[b] | | | |
| | | | | Mild | | Moderate | | Severe | | Not Related | | Related | |
| | | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | |

Note: N = Number of participants in the Safety Population.

[a]For severity, a participant is counted once per preferred term and is summarized according to the highest severity.

[b]For relationship, a participant is only counted once per preferred term and is summarized according to their closest relationship.

*Repeat for all treatment groups: ETVAX Full Dose + 10 µg dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.1b:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity, Relationship and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.1(a). Repeat for all treatment groups: ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX Full Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) 10 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.1c:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity, Relationship and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.1(a). Repeat for all treatment groups: ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.1d:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity, Relationship and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.1(a). Repeat for all treatment groups: ETVAX 1/8 Dose, ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.2a:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity and Treatment Group**

| ETVAX Full Dose (N=XX) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| MedDRA® System Organ Class | MedDRA® Preferred Term | Any Incidence | | Severity[a] | | | | | |
| | | | | Mild | | Moderate | | Severe | |
| | | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |

Note: N = Number of participants in the Safety Population.

[a]For severity, a participant is counted once per preferred term and is summarized according to the highest severity.

*Repeat for all treatment groups: ETVAX Full Dose + 10 µg dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.2b:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.2(a). Repeat for all treatment groups: ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX Full Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) 10 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.2c:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.2(a). Repeat for all treatment groups: ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.8.2d:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Maximum Severity and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.1.7.2(a). Repeat for all treatment groups: ETVAX 1/8 Dose, ETVAX 1/4 Dose, ETVAX 1/2 Dose, Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine, Placebo*

**TABLE 14.3.1.9.1a:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Adults**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX Full Dose | | | | ETVAX Full Dose + 10 µg dmLT | | | | Combined Vaccine | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Day 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.9.1b:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | | ETVAX Full Dose | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Day 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 1-80-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.9.1c:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | | Combined ETVAX Alone | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Day 0-7 (N=X) | | Days 8+ (N=X) | | Days 1-80-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.9.1d:**
**Number and Percentage of Participants Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/8 Dose | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Day 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.9.2a:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Adults**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX Full Dose | | | | ETVAX Full Dose + 10 µg dmLT | | | | Combined Vaccine | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Full Analysis population. For each time period, a participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.9.2b:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | | ETVAX Full Dose | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 1-80-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Full Analysis population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.9.2c:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | | Combined ETVAX Alone | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Full Analysis population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.9.2d:**
**Number and Percentage of Participants Experiencing Related Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | | | ETVAX 1/8 Dose | | | | ETVAX 1/4 Dose | | | | ETVAX 1/2 Dose | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | | Days 0-7 (N=X) | | Days 8+ (N=X) | |
| | | n | % | N | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Any SOC | Any PT | | | | | | | | | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | | | | | | | | | |
| | [PT 1] | | | | | | | | | | | | | | | | |
| | [PT 2] | | | | | | | | | | | | | | | | |

Note: N=Number of participants in the Full Analysis population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.10a:**
**Number of Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Adults**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | ETVAX Full Dose | | ETVAX Full Dose + 10 µg dmLT | | Combined Vaccine | |
|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | Days 8+ (N=X) | Days -0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) |
| | | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events |
| Any SOC | Any PT | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

**TABLE 14.3.1.10b:**
**Number of Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Toddlers (24 - 59 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | ETVAX 1/4 Dose | | ETVAX 1/2 Dose | | ETVAX Full Dose | |
|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) |
| | | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events |
| Any SOC | Any PT | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**TABLE 14.3.1.10c:**
**Number of Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Young Children (12 - 23 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | ETVAX 1/4 Dose | | ETVAX 1/2 Dose | | Combined ETVAX Alone | |
|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) |
| | | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events |
| Any SOC | Any PT | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

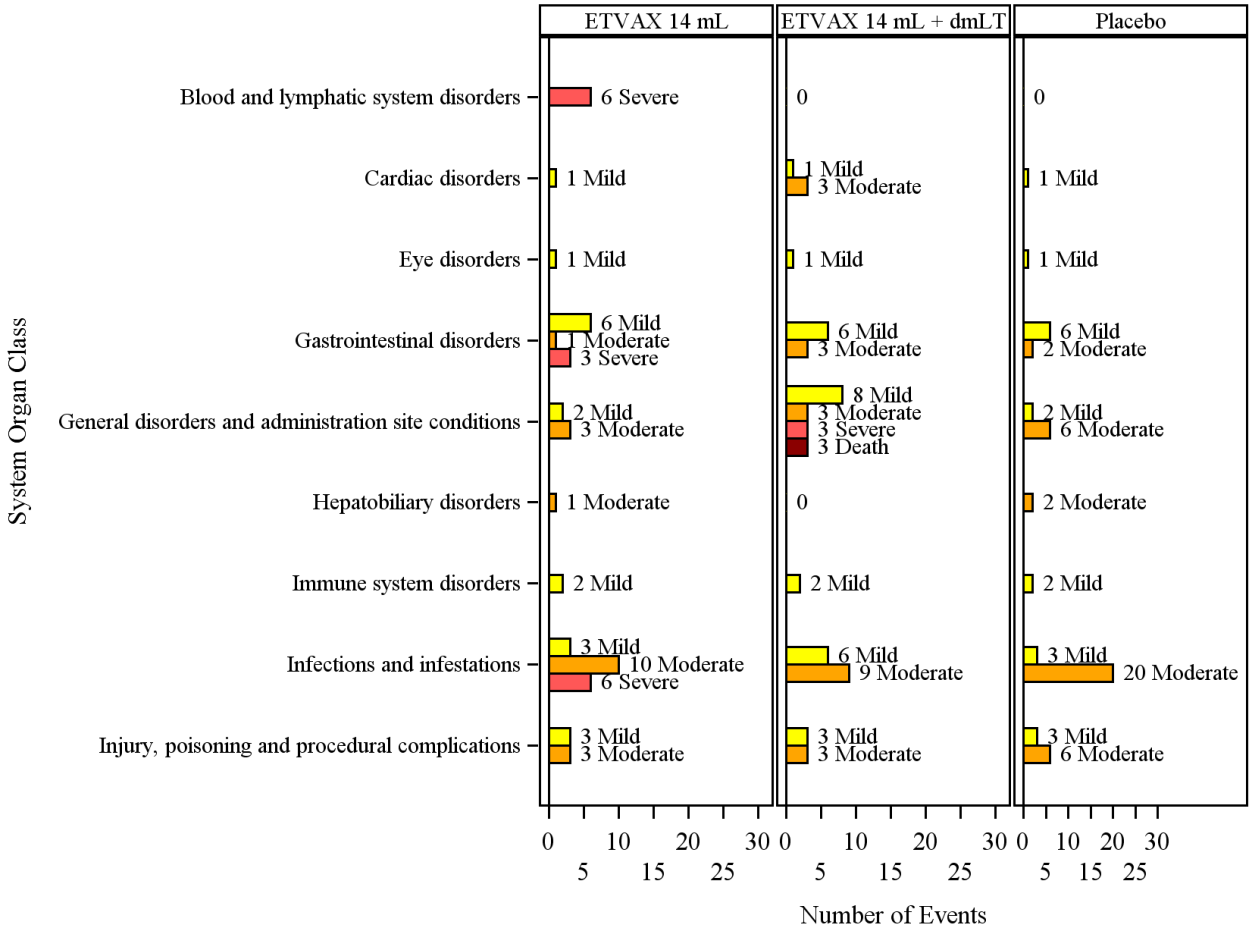
**TABLE 14.3.1.10d:**
**Number of Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Days Post Vaccination and Treatment Group - Infants (6 - 11 Months)**

| MedDRA® System Organ Class | MedDRA® Preferred Term | Placebo | | ETVAX 1/8 Dose | | ETVAX 1/4 Dose | | ETVAX 1/2 Dose | |
|---|---|---|---|---|---|---|---|---|---|
| | | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) | Days 0-7 (N=X) | Days 8+ (N=X) |
| | | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events | # of Events |
| Any SOC | Any PT | | | | | | | | |
| [SOC 1] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |
| [SOC 2] | Any PT | | | | | | | | |
| | [PT 1] | | | | | | | | |
| | [PT 2] | | | | | | | | |

Note: N=Number of participants in the Safety population. For each time period, a participant is only counted once per preferred term and system organ class.

*Programming Note: Continue with the following treatments: Combined ETVAX Alone, ETVAX (highest safe dose) + 2.5µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, Combined ETVAX + dmLT, Combined Vaccine.*

**FIGURE 14.3.1.11a:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Adults**




*Programming Note: Continue for all MedDRA System Organ Classes.*

**FIGURE 14.3.1.11b:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.11b - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

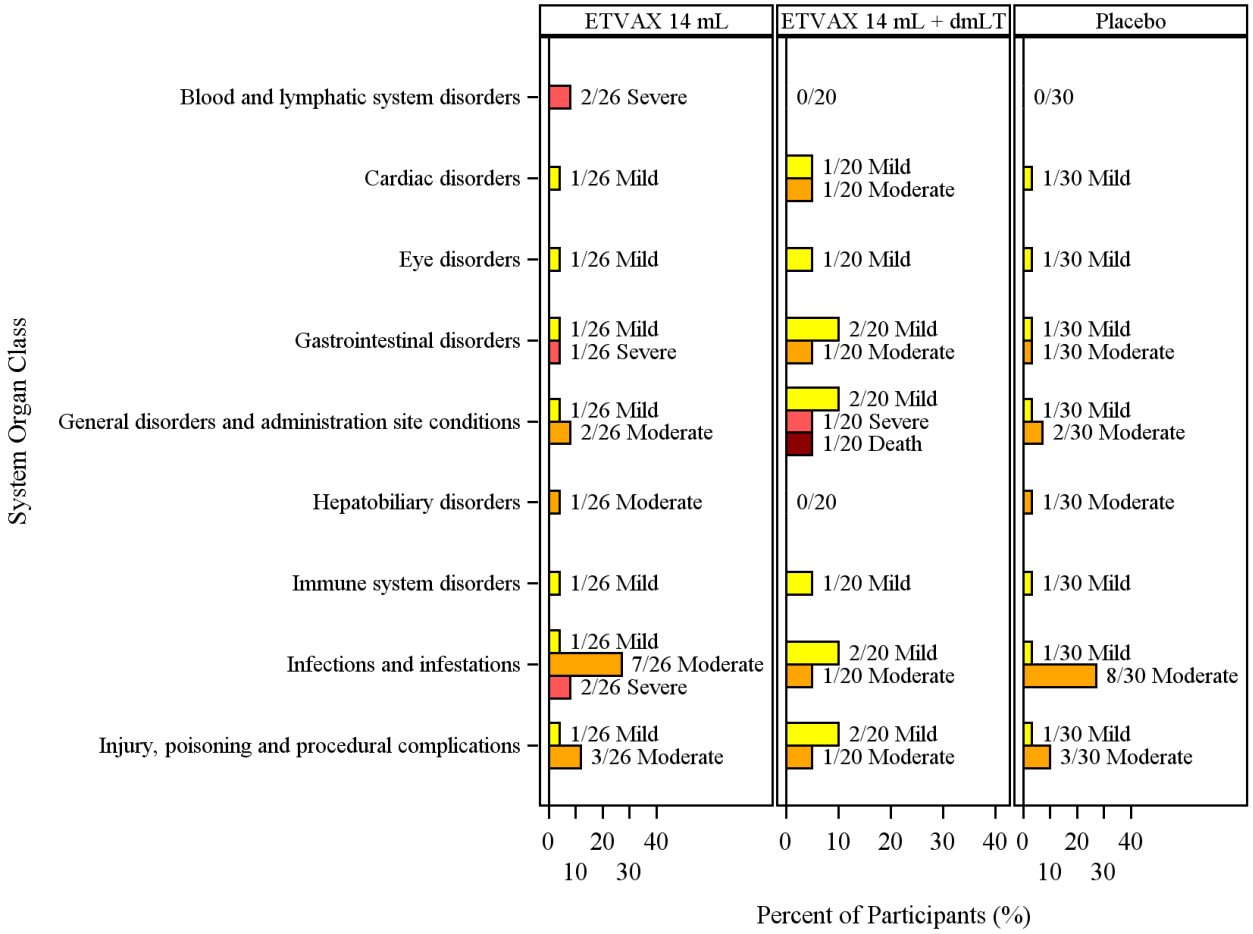
**FIGURE 14.3.1.11c:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.11c - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.11d:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.11d - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.12a:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Adults**




*Programming Note: Continue for all MedDRA System Organ Classes.*

**FIGURE 14.3.1.12b:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.12a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

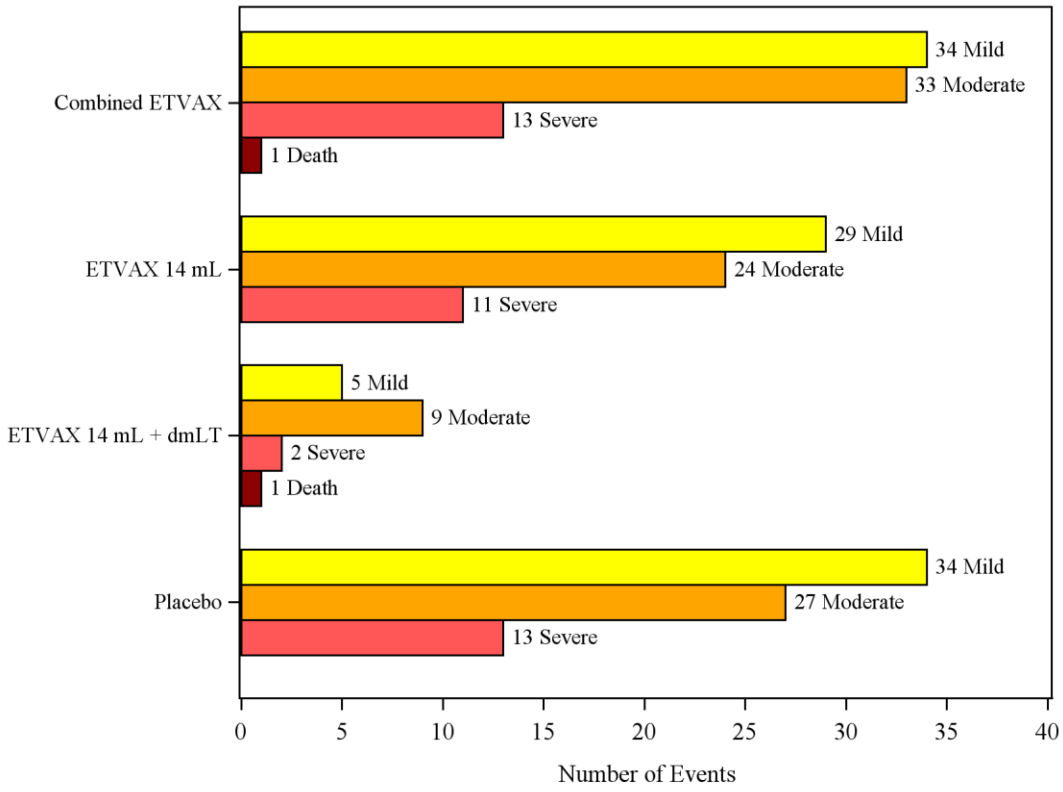
**FIGURE 14.3.1.12c:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.12c - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.12d:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Maximum Severity - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.12d - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.13a:**
**Frequency of Adverse Events by Severity - Adults**




*Note: This Figure includes serious and non-serious adverse events.*

**FIGURE 14.3.1.13b:**
**Frequency of Adverse Events by Severity - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.13a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

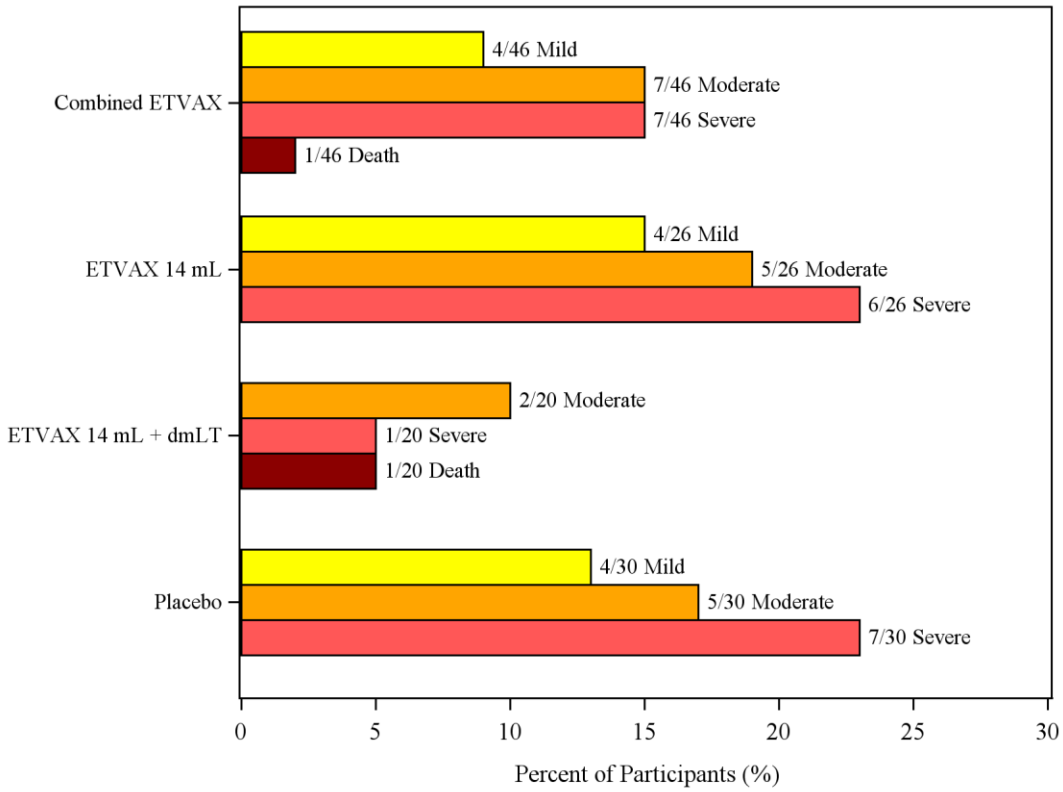
**FIGURE 14.3.1.13c:**
**Frequency of Adverse Events by Severity - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.13a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.13d:**
**Frequency of Adverse Events by Severity - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.13a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.14a:**
**Incidence of Adverse Events by Maximum Severity - Adults**




*Note: This figure includes both serious and non-serious unsolicited adverse events. The maximum severity for a participant will be summarized.*

**FIGURE 14.3.1.14b:**
**Incidence of Adverse Events by Severity - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.14a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

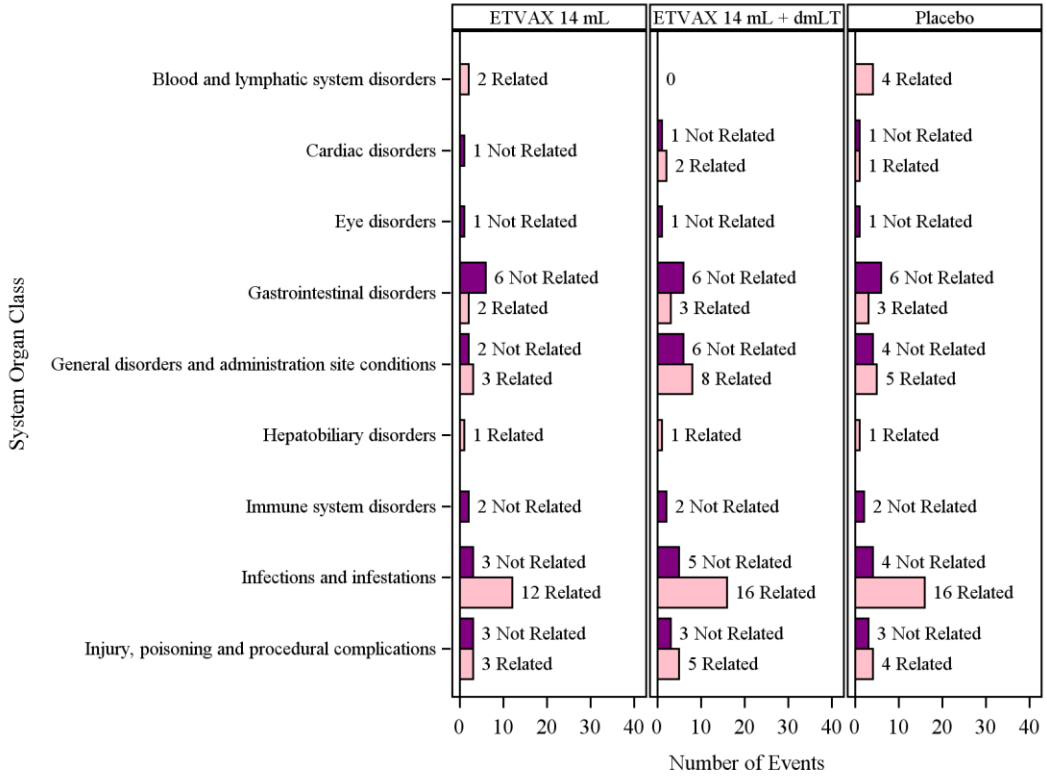
**FIGURE 14.3.1.14c:**
**Incidence of Adverse Events by Severity - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.14a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.14d:**
**Incidence of Adverse Events by Severity - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.14a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.15a:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Adults**




*Programing Note: Continue for all MedDRA system organ class.*

**FIGURE 14.3.1.15b:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.15a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

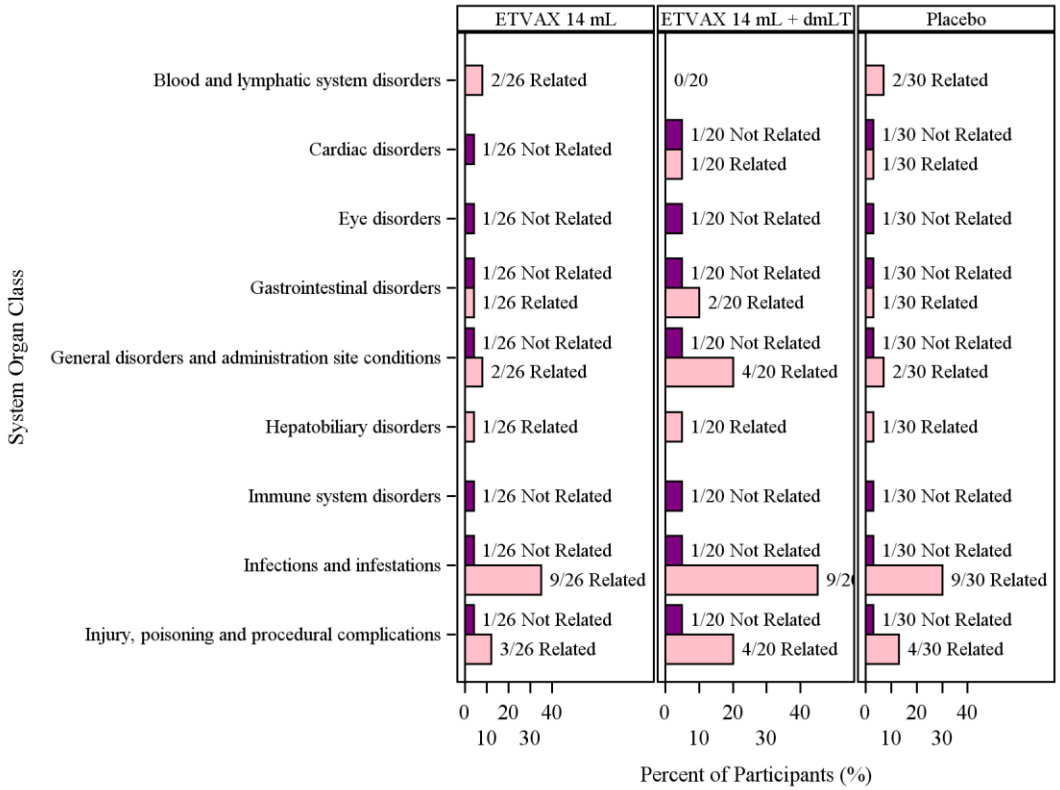
**FIGURE 14.3.1.15c:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.15c - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.15d:**
**Frequency of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.15d - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.16a:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Adults**




*Note: Continue for all MedDRA system organ class. The maximum relatedness is summarized for a participant*

**FIGURE 14.3.1.16b:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.16a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

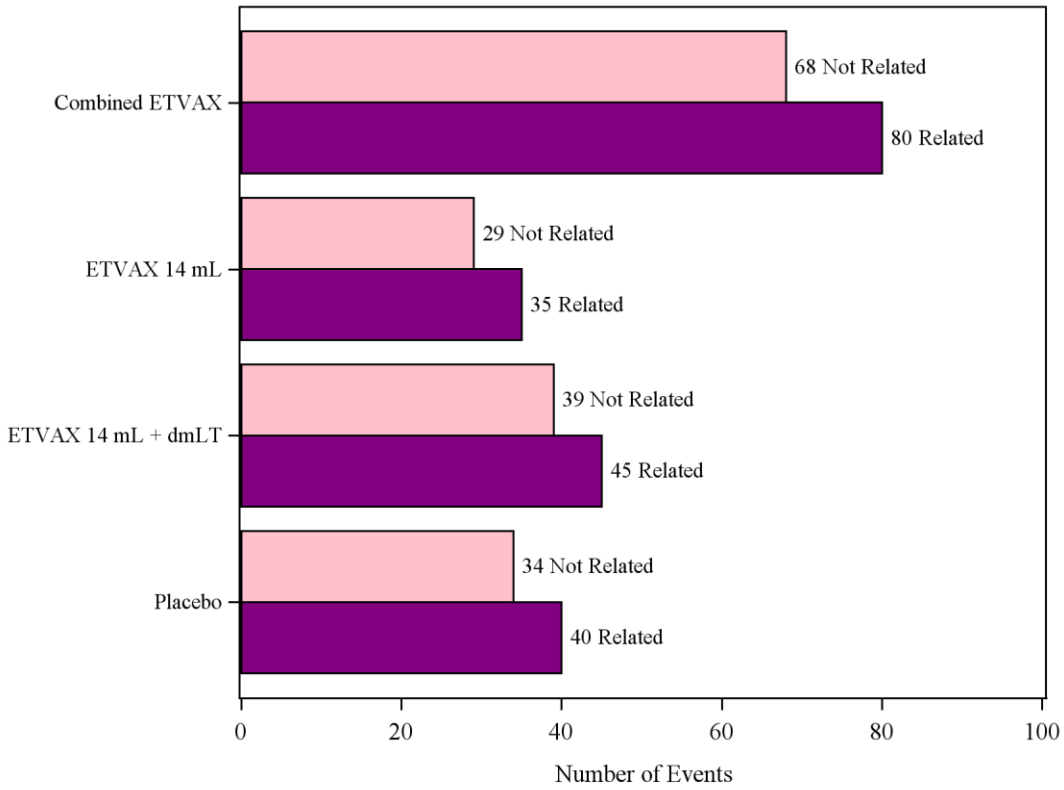
**FIGURE 14.3.1.16c:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.16c - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.16d:**
**Incidence of Non-Serious Adverse Events by MedDRA® System Organ Class and Relationship to Treatment - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.16d - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.17a:**
**Frequency of Adverse Events by Relationship to Treatment - Adults**




*Programming Note: This figure includes both serious and non-serious adverse events.*

**FIGURE 14.3.1.17b:**
**Frequency of Adverse Events by Relationship to Treatment - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.17a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

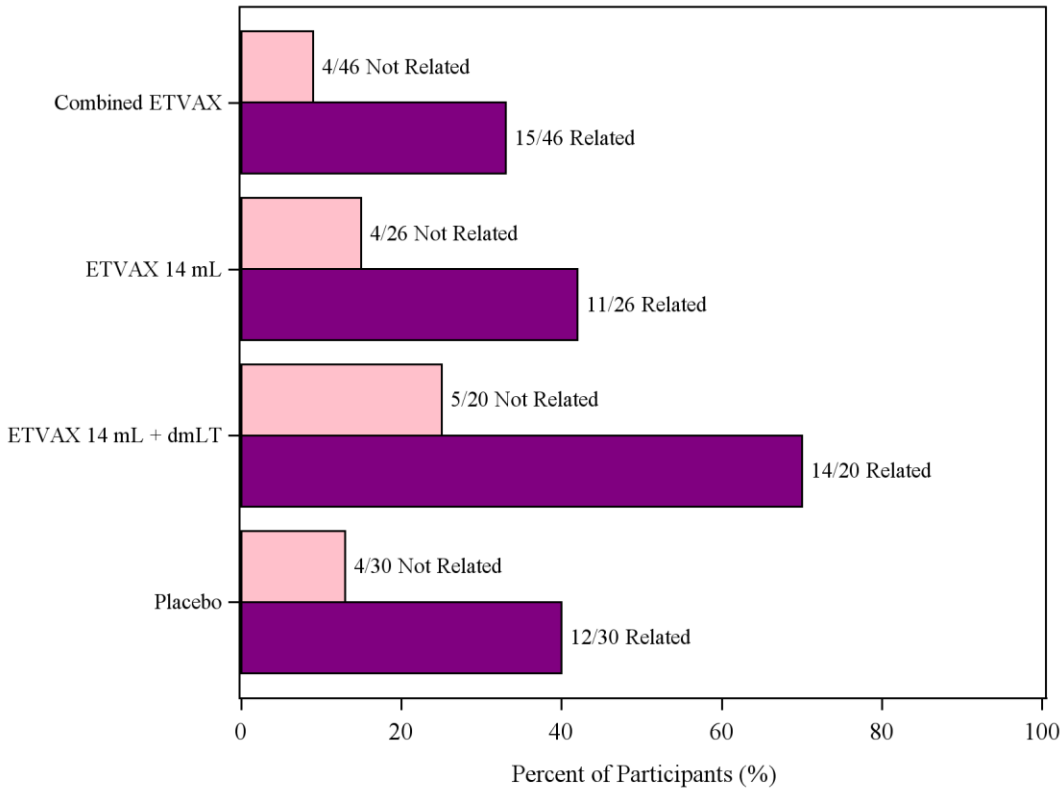
**FIGURE 14.3.1.17c:**
**Frequency of Adverse Events by Relationship to Treatment - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.17a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.17d:**
**Frequency of Adverse Events by Relationship to Treatment - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.17a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.18a:**
**Incidence of Adverse Events by Relationship to Treatment - Adults**




*Programming Note: This figure includes both serious and non-serious adverse events. The max relatedness for a participant is summarized.*

**FIGURE 14.3.1.18b:**
**Incidence of Adverse Events by Relationship to Treatment - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.1.18a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

**FIGURE 14.3.1.18c:**
**Incidence of Adverse Events by Relationship to Treatment - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.1.18a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.1.18d:**
**Incidence of Adverse Events by Relationship to Treatment - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.1.18a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**TABLE 14.3.2.1a:**
**Listing of Deaths, Serious Adverse Events and Other Significant Events - Adults**

| Participant ID | Age | Treatment Group | Onset Date | Adverse Event | # of Days Post Dose (Dose #) | Duration (Days) | Reason Reported as an SAE | Severity | Relationship to Study Treatment |
|---|---|---|---|---|---|---|---|---|---|

| Participant ID | Adverse Event | Action Taken with Study Treatment | Outcome | Comments |
|---|---|---|---|---|
| | | | | |
| | | | | |

**TABLE 14.3.2.1b:**
**Listing of Deaths, Serious Adverse Events and Other Significant Events - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.1(a).*

**TABLE 14.3.2.1c:**
**Listing of Deaths, Serious Adverse Events and Other Significant Events - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.1(a).*

**TABLE 14.3.2.1d:**
**Listing of Deaths, Serious Adverse Events and Other Significant Events - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.1(a).*

**TABLE 14.3.2.2a:**
**Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events - Adults**

| Participant ID | Treatment Group | Onset Date | Adverse Event | # of Days Post Dose (Dose #) | Duration (Days) | Severity | Relationship to Study Treatment | Action Taken with Study Treatment |
|---|---|---|---|---|---|---|---|---|

| Participant ID | Adverse Event | Outcome | Comments |
|---|---|---|---|
| | | | |
| | | | |

**TABLE 14.3.2.2b:**
**Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.2(a).*

**TABLE 14.3.2.2c:**
**Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.2(a).*

**TABLE 14.3.2.2d:**
**Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.2.2(a).*

## Section 14.3.3: Narratives of Deaths, Other Serious and Significant Adverse Events

[This is a place holder for this section in the CSR]

## TABLE 14.3.4.1a:
## Laboratory Results by Parameter, Maximum Severity, Study Day, and Treatment Group - Adults

| Any Laboratory Parameter | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Mild/ Grade 1 | | | | Moderate/ Grade 2 | | | | Severe/Grade 3 | | | | Life Threatening/ Grade 4 | | | | | |
| | | | None | | (Low) | | (High) | | (Low) | | (High) | | (Low) | | (High) | | (Low) | | (High) | | Missing | |
| Time Point | Treatment Group | N | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

Note: The "Max Post Baseline" row indicate the maximum severity experienced by each participant at any time point post baseline, including unscheduled assessments.
N = Number of participants in the Safety population.

**Table 14.3.4.1a: continued**
**Laboratory Results by Parameter, Maximum Severity, Study Day and Treatment Group - Adults**

| Hemoglobin (g/dL) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Time Point | Treatment Group | N | None | | Mild/ Grade 1 (Low) | | Moderate/ Grade 2 (Low) | | Severe/ Grade 3 (Low) | | Life-Threatening/ Grade 4 (Low) | | Missing | |
| | | | n | % | n | % | n | % | n | % | n | % | n | % |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

**Table 14.3.4.1a: continued**
**Laboratory Results by Parameter, Maximum Severity, Study Day and Treatment Group - Adults**

| Platelet Counts ($10^9$/L) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Time Point | Treatment Group | N | None | | Mild/ Grade 1 (Low) | | Moderate/ Grade 2 (Low) | | Severe/ Grade 3 (Low) | | Life-Threatening/ Grade 4 (Low) | | Missing | |
| | | | n | % | n | % | n | % | n | % | n | % | n | % |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

**Table 14.3.4.1a: continued**
**Laboratory Results by Parameter, Maximum Severity, Study Day and Treatment Group - Adults**

| White Blood Cells $10^9$/L | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Mild/ Grade 1 | | | | Moderate/ Grade 2 | | | | Severe/Grade 3 | | | | Life Threatening/ Grade 4 | | | | | |
| | | | None | | (Low) | | (High) | | (Low) | | (High) | | (Low) | | (High) | | (Low) | | (High) | | Missing | |
| Time Point | Treatment Group | N | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

Note: The "Max Post Baseline" row indicate the maximum severity experienced by each participant at any time point post baseline, including unscheduled assessments.
N = Number of participants in the Safety population.

**Table 14.3.4.1a: continued**
**Laboratory Results by Parameter, Maximum Severity, Study Day and Treatment Group - Adults**

| Alanine Aminotransferase (ALT) (U/L) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Time Point | Treatment Group | N | None | | Mild/ Grade 1 (High) | | Moderate/ Grade 2 (High) | | Severe/ Grade 3 (High) | | Severe/ Grade 4 (High) | | Missing | |
| | | | n | % | n | % | n | % | n | % | n | % | n | % |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

**Table 14.3.4.1a: continued**
**Laboratory Results by Parameter, Maximum Severity, Study Day and Treatment Group - Adults**

| Creatinie (µmol/L) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Time Point** | **Treatment Group** | **N** | **None** | | **Mild/ Grade 1 (High)** | | **Moderate/ Grade 2 (High)** | | **Severe/ Grade 3 (High)** | | **Severe/ Grade 4 (High)** | | **Missing** | |
| | | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Day 7 | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| Max Severity Post Baseline | Placebo | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | ETVAX Full Dose + 10 µg dmLT | x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |

**TABLE 14.3.4.1b:**
**Laboratory Results by Parameter, Maximum Severity, Study Day, and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.1(a). Treatments to summarize are the following: Placebo, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX Full Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT*

**TABLE 14.3.4.1c:**
**Laboratory Results by Parameter, Maximum Severity, Study Day, and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.1(a). Treatments to summarize are the following: Placebo, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT*

**TABLE 14.3.4.1d:**
**Laboratory Results by Parameter, Maximum Severity, Study Day, and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.1(a). Treatments to summarize are the following: Placebo, ETVAX 1/8 Dose, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT*

**TABLE 14.3.4.2a:**
**Summary Statistics of Laboratory Results by Parameter, Study Visit and Treatment Group - Adults**

| Laboratory Parameter | Time Point | Treatment Group | N | Mean | Standard Deviation | Median | 25th - 75th Percentile | Min, Max |
|---|---|---|---|---|---|---|---|---|
| Hemoglobin (g/dL) | Baseline | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | Day 7 | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | Day 7, Change from Baseline | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | | | | | | | |
| Platelet Count ($10^9$/L) | Baseline | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | Day 7 | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | Day 7, Change from Baseline | Placebo | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |
| | | ETVAX Full Dose + 10 µg dmLT | x | xx.x | xx.x | xx.x | xx.x - xx.x | xx.x, xx.x |

*Note: Continue for all laboratory tests: White Blood Cells ($10^9$/L), ALT (U/L), Creatinine (µmol/L).*

**TABLE 14.3.4.2b:**
**Summary Statistics of Laboratory Results by Parameter, Study Visit and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.2(a). Treatments to summarize are the following: Placebo, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX Full Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT, ETVAX (highest safe dose) + 10 µg dmLT*

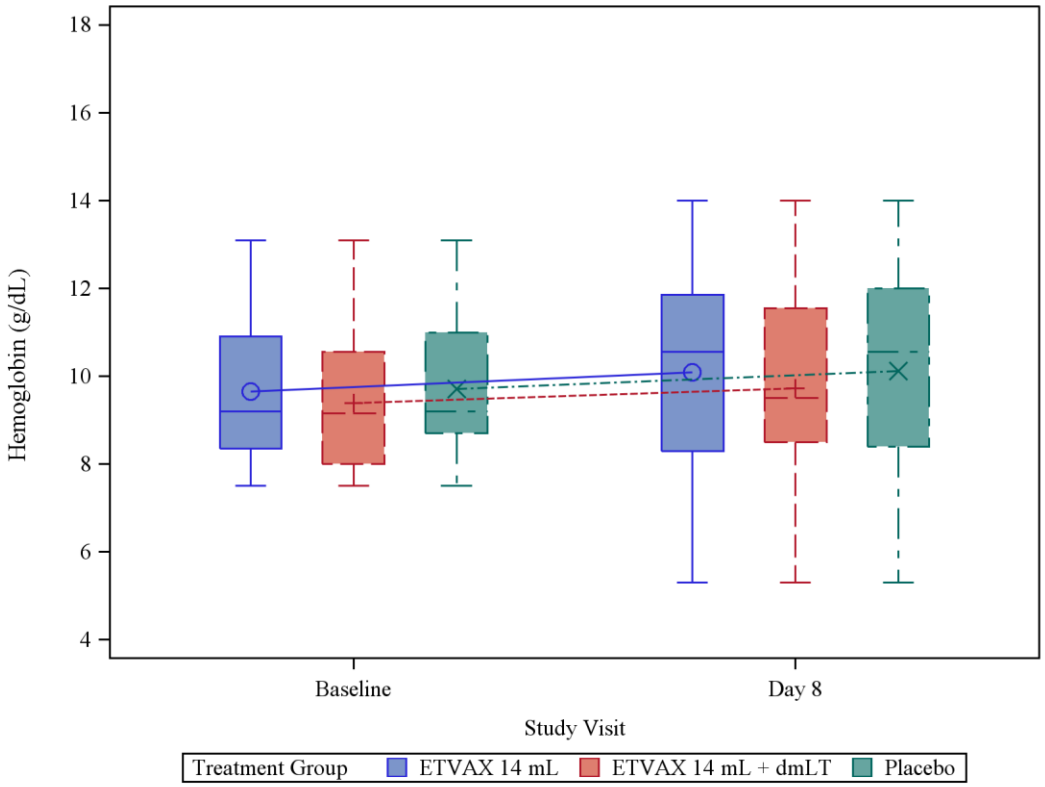
**TABLE 14.3.4.2c:**
**Summary Statistics of Laboratory Results by Parameter, Study Visit and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.2(a). Treatments to summarize are the following: Placebo, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT*

**TABLE 14.3.4.2d:**
**Summary Statistics of Laboratory Results by Parameter, Study Visit and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.2(a). Treatments to summarize are the following: Placebo, ETVAX 1/8 Dose, ETVAX 1/4 Dose, ETVAX 1/2 Dose, ETVAX (highest safe dose) + 2.5 µg dmLT, ETVAX (highest safe dose) + 5 µg dmLT*

**FIGURE 14.3.4.3a:**
**Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter and Treatment Group - Adults**




*Note: Continue for all laboratory tests: Platelet Counts ($10^9$/L), White Blood Cells ($10^9$/L), Alanine Aminotransferase (ALT) (U/L), Creatinine (mg/dL)*

**FIGURE 14.3.4.3b:**
**Laboratory Results by Scheduled Visits: Mean Changes from Baseline**
**by Laboratory Parameter and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.4.3a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

**FIGURE 14.3.4.3c:**
**Laboratory Results by Scheduled Visits: Mean Changes from Baseline**
**by Laboratory Parameter and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.4.3a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.4.3d:**
**Laboratory Results by Scheduled Visits: Mean Changes from Baseline**
**by Laboratory Parameter and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.4.3a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

## TABLE 14.3.4.4a:
## Listing of Abnormal Laboratory Results - Adults

| Participant ID | Arm | Sex | Age (years) | Planned Time Point | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Treatment | If Not Related, Alternate Etiology | Action Taken with Study Treatment | Participant Discontinued Due to Result? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

[Implementation Note: This listing only includes abnormal laboratory results. A complete listing of all laboratory results is included in the listings document. In the Laboratory Parameter column, indicate the units after the parameter, e.g., Hemoglobin (g/dL).
The grade will be included in parentheses after the result, e.g., 16.2 (Grade 1).]

## TABLE 14.3.4.4b:
## Listing of Abnormal Laboratory Results - Toddlers (24 - 59 Months)

| Participant ID | Arm | Sex | Age (months) | Planned Time Point | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Treatment | If Not Related, Alternate Etiology | Action Taken with Study Treatment | Participant Discontinued Due to Result? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

[Implementation Note: This listing only includes abnormal laboratory results. A complete listing of all laboratory results is included in the listings document. In the Laboratory Parameter column, indicate the units after the parameter, e.g., Hemoglobin (g/dL).
The grade will be included in parentheses after the result, e.g., 16.2 (Grade 1).]

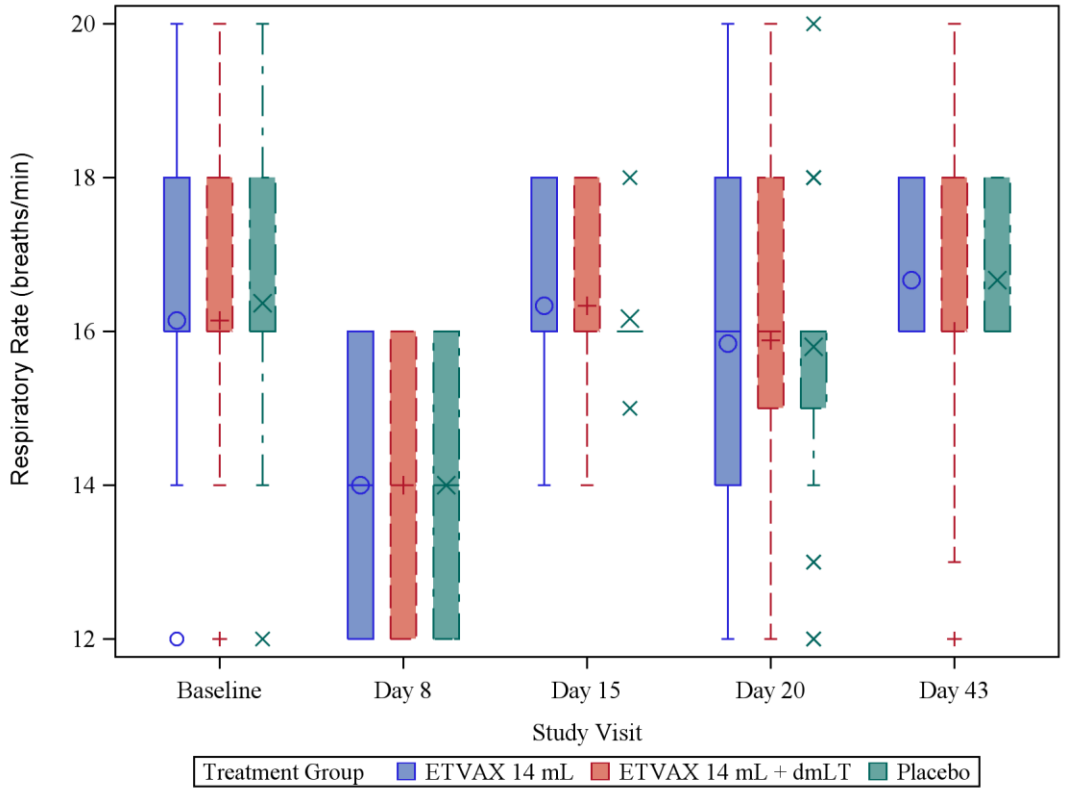
**TABLE 14.3.4.4c:**
**Listing of Abnormal Laboratory Results - Young Children (12 - 23 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.4(b).*

**TABLE 14.3.4.4d:**
**Listing of Abnormal Laboratory Results - Infants (6 - 11 Months)**

*Programming Note: Use the same Table shell as Table 14.3.4.4(b).*

**FIGURE 14.3.5.1a:**
**Vital Sign Measurements by Scheduled Visits: Mean Changes from Baseline by Vital Sign and Treatment Group - Adults**




*Note: Continue for all vital signs: Heart Rate (beats/min)*

**FIGURE 14.3.5.1b:**
**Vital Sign Measurements by Scheduled Visits: Mean Changes from Baseline by Vital Sign and Treatment Group - Toddlers (24 - 59 Months)**

*Programming Note: Use same format as Figure 14.3.5.1a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX 14 mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, ETVAX ## + 10 µg dmLT, Placebo*

**FIGURE 14.3.5.1c:**
**Vital Sign Measurements by Scheduled Visits: Mean Changes from Baseline by Vital Sign and Treatment Group - Young Children (12 - 23 Months)**

*Programming Note: Use same format as Figure 14.3.5.1a - except use treatment groups: ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**FIGURE 14.3.5.1d:**
**Vital Sign Measurements by Scheduled Visits: Mean Changes from Baseline by Vital Sign and Treatment Group - Infants (6 - 11 Months)**

*Programming Note: Use same format as Figure 14.3.5.1a - except use treatment groups: ETVAX 1.75 mL, ETVAX 3.5 mL, ETVAX 7mL, ETVAX ## + 2.5 µg dmLT, ETVAX ## + 5 µg dmLT, Placebo*

**TABLE 14.3.6a:**
**Number and Percentage of Participants with Prior and Concurrent Medications by Treatment Group - Adults**

| Medication Name | Placebo (N=X) | | ETVAX Full Dose (N=X) | | ETVAX Full Dose + 10 µg dmLT (N=X) | | All Participants (N=X) | |
|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

**TABLE 14.3.6b:**
**Number and Percentage of Participants with Prior and Concurrent Medications by Treatment Group - Toddlers (24 - 59 Months)**

| Medication Name | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | ETVAX Full Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

| Medication Name | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +10 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

**TABLE 14.3.6c:**
**Number and Percentage of Participants with Prior and Concurrent Medications by Treatment Group - Young Children (12 - 23 Months)**

| | Placebo (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| **Medication Name** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

| | ETVAX (highest safe dose) +2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) +5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| **Medication Name** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

## TABLE 14.3.6d:
## Number and Percentage of Participants with Prior and Concurrent Medications by Treatment Group - Infants (6 - 11 Months)

| | Placebo (N=XX) | | ETVAX 1/8 Dose (N=XX) | | ETVAX 1/4 Dose (N=XX) | | ETVAX 1/2 Dose (N=XX) | | Combined ETVAX Alone (N=XX) | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Medication Name** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

| | ETVAX (highest safe dose) + 2.5 µg dmLT (N=XX) | | ETVAX (highest safe dose) + 5 µg dmLT (N=XX) | | Combined ETVAX + dmLT (N=XX) | | All Participants (N=XX) | |
|---|---|---|---|---|---|---|---|---|
| **Medication Name** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Any Medication | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 1] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 2] | x | x.x | x | x.x | x | x.x | x | x.x |
| [Medication 3] | x | x.x | x | x.x | x | x.x | x | x.x |
| | | | | | | | | |

N = Number of participants in the Safety population. n = Number of participants reporting taking at least one medication in the medication class. A participant will only be counted once in each row.

## 14.2 DATA LISTINGS

**LISTING 16.2.1a:**
**Early Terminations or Discontinued Participants - Adults**

| Participant ID | Treatment Group | Category | Reason for Early Termination | Study Day |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

**LISTING 16.2.1b:**
**Early Terminations or Discontinued Participants - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.1a shell.*

**LISTING 16.2.1c:**
**Early Terminations or Discontinued Participants - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.1a shell.*

**LISTING 16.2.1d:**
**Early Terminations or Discontinued Participants - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.1a shell.*

**LISTING 16.2.2.1a:**
**Participant-Specific Protocol Deviations - Adults**

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

**LISTING 16.2.2.1b:**
**Participant-Specific Protocol Deviations - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.2.1a shell.*

**LISTING 16.2.2.1c:**
**Participant-Specific Protocol Deviations - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.2.1a shell.*

**LISTING 16.2.2.1d:**
**Participant-Specific Protocol Deviations - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.2.1a shell.*

**LISTING 16.2.2.2a:**
**Non-Participant-Specific Protocol Deviations - Adults**

| Site | Deviation | Start Date | End Date | Reason for Deviation | Deviation Resulted in Participant Termination? | Deviation Affected Product Stability? | Deviation Category | Deviation Resolution | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |

**LISTING 16.2.2.2b:**
**Non-Participant-Specific Protocol Deviations - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.2.2a shell.*

**LISTING 16.2.2.2c:**
**Non-Participant-Specific Protocol Deviations - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.2.2a shell.*

**LISTING 16.2.2.2d:**
**Non-Participant-Specific Protocol Deviations - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.2.2a shell.*

**LISTING 16.2.3a:**
**Participants Excluded from the Immunogenicity Analysis - Adults**

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

**LISTING 16.2.3b:**
**Participants Excluded from the Immunogenicity Analysis - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.3a shell.*

**LISTING 16.2.3c:**
**Participants Excluded from the Immunogenicity Analysis - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.3a shell.*

**LISTING 16.2.3d:**
**Participants Excluded from the Immunogenicity Analysis - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.3a shell.*

## LISTING 16.2.4.1a:
## Demographic Data - Adults

| Participant ID | Treatment Group | Sex | Age at Enrollment (years) | Ethnicity | Race | Height at Enrollment (cm) | Weight at Enrollment (kg) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## LISTING 16.2.4.1b:
## Demographic Data - Toddlers (24 - 59 Months)

| Participant ID | Treatment Group | Sex | Age at Enrollment (months) | Ethnicity | Race | Length at Enrollment (cm) | Weight at Enrollment (kg) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## LISTING 16.2.4.1c:
## Demographic Data - Young Children (12 - 23 Months)

| Participant ID | Treatment Group | Sex | Age at Enrollment (months) | Ethnicity | Race | Length at Enrollment (cm) | Weight at Enrollment (kg) | Gestational Age at Delivery (weeks) | Birth Weight (kg) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

## LISTING 16.2.4.1d:
## Demographic Data - Infants (6 - 11 Months)

| Participant ID | Treatment Group | Sex | Age at Enrollment (months) | Ethnicity | Race | Length at Enrollment (cm) | Weight at Enrollment (kg) | Gestational Age at Delivery (weeks) | Birth Weight (kg) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
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## LISTING 16.2.4.2a:
## Pre-Existing Medical Conditions - Adults

| Participant ID | Treatment Group | MH Number | Medical History Term | Condition Start Day | Condition End Day | MedDRA® System Organ Class | MedDRA® Preferred Term |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

[Implementation Note: "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). Rather than use exact study days, categorize as follows:

- > 5 years prior to enrollment
- 1-5 years prior to enrollment
- 1-12 months prior to enrollment
- Within 1 month of enrollment
- During study
- If ongoing, display "Ongoing" in the "Condition End Day" column]

## LISTING 16.2.4.2b:
## Pre-Existing Medical Conditions - Toddlers (24 - 59 Months)

| Participant ID | Treatment Group | MH Number | Medical History Term | Condition Start Day | Condition End Day | MedDRA® System Organ Class | MedDRA® Preferred Term |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

[Implementation Note: "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). Rather than use exact study days, categorize as follows:

- > 1 year prior to enrollment
- 1-12 months prior to enrollment
- Within 1 month of enrollment
- During study
- If ongoing, display "Ongoing" in the "Condition End Day" column]

## LISTING 16.2.4.2c:
## Pre-Existing Medical Conditions - Young Children (12 - 23 Months)

| Participant ID | Treatment Group | MH Number | Medical History Term | Condition Start Day | Condition End Day | MedDRA® System Organ Class | MedDRA® Preferred Term |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

[Implementation Note: "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). Rather than use exact study days, categorize as follows:

- > 6 months prior to enrollment
- 1-5 months prior to enrollment
- Within 1 month of enrollment
- During study
- If ongoing, display "Ongoing" in the "Condition End Day" column]

## LISTING 16.2.4.2d:
## Pre-Existing Medical Conditions - Infants (6 - 11 Months)

| Participant ID | Treatment Group | MH Number | Medical History Term | Condition Start Day | Condition End Day | MedDRA® System Organ Class | MedDRA® Preferred Term |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

[Implementation Note: "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). Rather than use exact study days, categorize as follows:

- > 1 month prior to enrollment
- Within 1 month of enrollment
- During study
- If ongoing, display "Ongoing" in the "Condition End Day" column]

## LISTING 16.2.5a:
## Compliance Information/Vaccination Dates - Adults

| Participant ID | Treatment Group | Vaccination Dates | | Both doses the same ? |
|---|---|---|---|---|
| | | First | Second | |
| | | | | Y/N |
| | | | | |
| | | | | |
| | | | | |

## LISTING 16.2.5b:
## Compliance Information/Vaccination Dates - Toddlers (24 - 59 Months)

| Participant ID | Treatment Group | Vaccination Dates | | Both doses the same ? |
|---|---|---|---|---|
| | | First | Second | |
| | | | | Y/N |
| | | | | |
| | | | | |
| | | | | |

**LISTING 16.2.5c:**
**Compliance Information/Vaccination Dates - Young Children (12 - 23 Months)**

| Participant ID | Treatment Group | Vaccination Dates | | Both doses the same ? |
|---|---|---|---|---|
| | | First | Second | |
| | | | | Y/N |
| | | | | |
| | | | | |
| | | | | |

**LISTING 16.2.5d:**
**Compliance Information/Vaccination Dates - Infants (6 - 11 Months)**

| Participant ID | Treatment Group | Vaccination Dates | | Both doses the same ? |
|---|---|---|---|---|
| | | First | Second | |
| | | | | Y/N |
| | | | | |
| | | | | |
| | | | | |

**LISTING 16.2.6.1a:**
**Individual Immunogenicity Response Data for Antibody Lymphocyte Secretion IgA - Adults**

| Participant ID | Treatment Group | Planned Time Point | Actual Study Day | Antigen | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | LTB | CFA/I | CS3 | CS6 | CS5 | 078 LPS |
| | | | | | | | | | |
| | | | | | | | | | |
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| | | | | | | | | | |
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**LISTING 16.2.6.1b:**
**Individual Immunogenicity Response Data for Antibody Lymphocyte Secretion IgA - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.6.1a shell.*

**LISTING 16.2.6.1c:**
**Individual Immunogenicity Response Data for Antibody Lymphocyte Secretion IgA - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.6.1a shell.*

**LISTING 16.2.6.1d:**
**Individual Immunogenicity Response Data for Antibody Lymphocyte Secretion IgA - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.6.1a shell.*

**LISTING 16.2.6.2a:**
**Individual Immunogenicity Response Data for Fecal Secretion IgA - Adults**

| Participant ID | Treatment Group | Planned Time Point | Actual Study Day | Antigen | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | LTB | CFA/I | CS3 | CS6 | CS5 | 078 LPS |
| | | | | | | | | | |
| | | | | | | | | | |
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**LISTING 16.2.6.2b:**
**Individual Immunogenicity Response Data for Fecal Secretion IgA - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.2c:**
**Individual Immunogenicity Response Data for Fecal Secretion IgA - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.2d:**
**Individual Immunogenicity Response Data for Fecal Secretion IgA - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.3a:**
**Individual Immunogenicity Response Data for Plasma ELISA - Adults**

| Participant ID | Treatment Group | Planned Time Point | Actual Study Day | IgA Antigen | | | | | | IgG Antigen | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | LTB | CFA/I | CS3 | CS6 | CS5 | 078 LPS | LTB | 078 LPS |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
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**LISTING 16.2.6.3b:**
**Individual Immunogenicity Response Data for Plasma ELISA - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.3c:**
**Individual Immunogenicity Response Data for Plasma ELISA - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.3d:**
**Individual Immunogenicity Response Data for Plasma ELISA - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.6.2a shell.*

**LISTING 16.2.6.4a:**
**Individual Data for T cell and Other Immune Responses - Adults**

| Participant ID | Treatment Group | Assay | Planned Time Point | Actual Study Day | Antigen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | LTB | CFA/I | CS3 | CS6 | CS5 |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

**LISTING 16.2.6.4b:**
**Individual Data for T cell and Other Immune Responses - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.6.4a shell.*

**LISTING 16.2.6.4c:**
**Individual Data for T cell and Other Immune Responses - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.6.4a shell.*

**LISTING 16.2.6.4d:**
**Individual Data for T cell and Other Immune Responses - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.6.4a shell.*

## LISTING 16.2.7.1a:
## Solicited Events - Adults

| Participant ID | Treatment Group | Vaccination | Post Dose Day | Assessment* | Oral Temperature | Nausea | Vomiting | Loose Stools | Diarrhea | Abdominal Pain/Stomach Ache | Acute Systemic Allergic Reaction |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | MA | | | | | | | |
| | | | | Clinic | | | | | | | |

* MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.
Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

*[Implementation Note: To indicate severity for quantitative symptoms (e.g., temperature) measurements, include the grade in parentheses after the number, e.g., 100.7 (Mild).]*

## LISTING 16.2.7.1b:
## Solicited Events - Toddlers (24 - 59 Months)

| Participant ID | Treatment Group | Vaccination | Post Dose Day | Assessment* | Oral Temperature | Vomiting | Loose Stools | Diarrhea | Abdominal Pain/Stomach Ache | Acute Systemic Allergic Reaction |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | MA | | | | | | |
| | | | | Clinic | | | | | | |

* MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.
Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

*[Implementation Note: To indicate severity for quantitative symptoms (e.g., temperature) measurements, include the grade in parentheses after the number, e.g., 100.7 (Mild).]*

## LISTING 16.2.7.1c:
## Solicited Events - Young Children (12 - 23 Months)

| Participant ID | Treatment Group | Vaccination | Post Dose Day | Assessment* | Oral Temperature | Vomiting | Loose Stools | Diarrhea | Acute Systemic Allergic Reaction |
|---|---|---|---|---|---|---|---|---|---|
| | | | | MA | | | | | |
| | | | | Clinic | | | | | |

* MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.
Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

*[Implementation Note: To indicate severity for quantitative symptoms (e.g., temperature) measurements, include the grade in parentheses after the number, e.g., 100.7 (Mild).]*

## LISTING 16.2.7.1d:
## Solicited Events - Infants (6 - 11 Months)

| Participant ID | Treatment Group | Vaccination | Post Dose Day | Assessment* | Oral Temperature | Vomiting | Loose Stools | Diarrhea | Acute Systemic Allergic Reaction |
|---|---|---|---|---|---|---|---|---|---|
| | | | | MA | | | | | |
| | | | | Clinic | | | | | |

* MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.
Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

*[Implementation Note: To indicate severity for quantitative symptoms (e.g., temperature) measurements, include the grade in parentheses after the number, e.g., 100.7 (Mild).]*

## LISTING 16.2.7.2a:
## Unsolicited Adverse Events - Adults

| Participant ID | Treatment Group | AE Number | Adverse Event | # of Days Post Dose (Dose #) | Duration (Days) | Severity | SAE? | Relationship to Study Treatment | If Not Related, Alternate Etiology | Action Taken with Study Treatment |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |

| Participant ID | Adverse Event | Action Taken with Study Treatment | Participant Discontinued Due to AE | Outcome | MedDRA® System Organ Class | MedDRA® Preferred Term | Comments |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

Note: For additional details about SAEs, see Table: 14.3.2.1.

## LISTING 16.2.7.2b:
## Unsolicited Adverse Events - Toddlers (24 - 59 Months)

*Programming Note: Use the same format as Listing 16.2.7.2a shell.*

## LISTING 16.2.7.2c:
## Unsolicited Adverse Events - Young Children (12 - 23 Months)

*Programming Note: Use the same format as Listing 16.2.7.2a shell.*

## LISTING 16.2.7.2d:
## Unsolicited Adverse Events - Infants (6 - 11 Months)

*Programming Note: Use the same format as Listing 16.2.7.2a shell.*

## LISTING 16.2.8.1a:
## Individual Clinical Laboratory Results – Hematology - Adults

| Participant ID | Treatment Group | Sex | Age (years) | Planned Study Day | Actual Study Day | Hemoglobin (g/dL) | Platelets ($10^9$/L) | White Blood Cells ($10^9$/L) | Neutrophils ($10^9$/L) | Lymphocytes ($10^9$/L) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

[Implementation Note: This listing includes all laboratory results, scheduled and unscheduled. The severity should be included in parentheses after the result of the abnormal results (e.g., 16.2 (Mild)).]

## LISTING 16.2.8.1b:
## Individual Clinical Laboratory Results – Hematology - Toddlers (24 - 59 Months)

*Programming Note: Use the same format as Listing 16.2.8.1a shell.*

## LISTING 16.2.8.1c:
## Individual Clinical Laboratory Results – Hematology - Young Children (12 - 23 Months)

*Programming Note: Use the same format as Listing 16.2.8.1a shell.*

## LISTING 16.2.8.1d:
## Individual Clinical Laboratory Results – Hematology - Infants (6 - 11 Months)

*Programming Note: Use the same format as Listing 16.2.8.1a shell.*

## LISTING 16.2.8.2a:
## Individual Clinical Laboratory Results – Biochemistry - Adults

| Participant ID | Treatment Group | Sex | Age | Planned Study Day | Actual Study Day | ALT (IU/L) | Serum Creatinine (mg/dL) | Albumin (g/dL) | Total Bilirubin (mg/dL) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

[Implementation Note: This listing includes all laboratory results, scheduled and unscheduled. The severity should be included in parentheses after the result of the abnormal results (e.g., 16.2 (Mild)).]

## LISTING 16.2.8.2b:
## Individual Clinical Laboratory Results – Biochemistry - Toddlers (24 - 59 Months)

*Programming Note: Use the same format as Listing 16.2.8.2a shell.*

## LISTING 16.2.8.2c:
## Individual Clinical Laboratory Results – Biochemistry - Young Children (12 - 23 Months)

*Programming Note: Use the same format as Listing 16.2.8.2a shell.*

## LISTING 16.2.8.2d:
## Individual Clinical Laboratory Results – Biochemistry - Infants (6 - 11 Months)

*Programming Note: Use the same format as Listing 16.2.8.2a shell.*

**LISTING 16.2.8.3a:**
**Individual Clinical Laboratory Results – Serology - Adults**

| Participant ID | Treatment Group | Sex | Age (years) | Planned Study Day | Actual Study Day | HBsAg | Anti-HCV |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

[Implementation Note: This listing includes all laboratory results, scheduled and unscheduled.]

**LISTING 16.2.8.3b:**
**Individual Clinical Laboratory Results – Serology - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.8.3a shell.*

**LISTING 16.2.8.3c:**
**Individual Clinical Laboratory Results – Serology - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.8.3a shell.*

**LISTING 16.2.8.3d:**
**Individual Clinical Laboratory Results – Serology - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.8.3a shell.*

**LISTING 16.2.9.1a:**
**Vital Signs - Adults**

| Participant ID | Treatment Group | Planned Study Day | Actual Study Day | Temperature (°Celsius) | Heart Rate (beats/min) | Respiratory Rate (breaths/min) |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

[Implementation Note: This listing includes all vital sign assessments, scheduled and unscheduled.]

**LISTING 16.2.9.1b:**
**Vital Signs - Toddlers (24 - 59 Months)**

*Programming Note: Use the same format as Listing 16.2.9.1a shell.*

**LISTING 16.2.9.1c:**
**Vital Signs - Young Children (12 - 23 Months)**

*Programming Note: Use the same format as Listing 16.2.9.1a shell.*

**LISTING 16.2.9.1d:**
**Vital Signs - Infants (6 - 11 Months)**

*Programming Note: Use the same format as Listing 16.2.9.1a shell.*

## LISTING 16.2.9.2a:
## Physical Exam Findings - Adults

| Participant ID | Treatment Group | Planned Time Point | Actual Study Day | Body System | Abnormal Finding | Reported as AE? (AE Number) |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

[Implementation Note: This listing includes all physical exam findings, scheduled and unscheduled. If a participant does not have any findings upon examination, they will not be included in this listing.
If reported as an AE, display "Yes" with the AE Number in parentheses, e.g., "Yes (7)".]

## LISTING 16.2.9.2b:
## Physical Exam Findings - Toddlers (24 - 59 Months)

*Programming Note: Use the same format as Listing 16.2.9.2a shell.*

## LISTING 16.2.9.2c:
## Physical Exam Findings - Young Children (12 - 23 Months)

*Programming Note: Use the same format as Listing 16.2.9.2a shell.*

## LISTING 16.2.9.2d:
## Physical Exam Findings - Infants (6 - 11 Months)

*Programming Note: Use the same format as Listing 16.2.9.2a shell.*

## LISTING 16.2.10a:
## Concomitant Medications - Adults

| Participant ID | Treatment Group | CM Number | Medication | Medication Start Day | Medication End Day | Indication | Taken for an AE? (AE Number) | Taken for a condition on Medical History? (MH Number) |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
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*[Implementation Note: "Medication Start Day" and "Medication End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact study days, categorize as follows:*

- *>5 years prior to enrollment*
- *1-5 years prior to enrollment*
- *1-12 months prior to enrollment*

*If ongoing, display "Ongoing" in the "Medication End Day" column.*
*If taken for an AE or MH, display "Yes" with the AE or MH Number in parentheses, e.g., "Yes (7)".]*

**LISTING 16.2.10b:**
**Concomitant Medications - Toddlers (24 - 59 Months)**

| Participant ID | Treatment Group | CM Number | Medication | Medication Start Day | Medication End Day | Indication | Taken for an AE? (AE Number) | Taken for a condition on Medical History? (MH Number) |
|---|---|---|---|---|---|---|---|---|
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*[Implementation Note: "Medication Start Day" and "Medication End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact study days, categorize as follows:*

- > 1 year prior to enrollment
- 1-12 months prior to enrollment

*If ongoing, display "Ongoing" in the "Medication End Day" column.*
*If taken for an AE or MH, display "Yes" with the AE or MH Number in parentheses, e.g., "Yes (7)".]*

**LISTING 16.2.10c:**
**Concomitant Medications - Young Children (12 - 23 Months)**

| Participant ID | Treatment Group | CM Number | Medication | Medication Start Day | Medication End Day | Indication | Taken for an AE? (AE Number) | Taken for a condition on Medical History? (MH Number) |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
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*[Implementation Note: "Medication Start Day" and "Medication End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact study days, categorize as follows:*

- > 6 months prior to enrollment
- 1-5 months prior to enrollment

*If ongoing, display "Ongoing" in the "Medication End Day" column.*
*If taken for an AE or MH, display "Yes" with the AE or MH Number in parentheses, e.g., "Yes (7)".]*

**LISTING 16.2.10d:**
**Concomitant Medications - Infants (6 - 11 Months)**

| Participant ID | Treatment Group | CM Number | Medication | Medication Start Day | Medication End Day | Indication | Taken for an AE? (AE Number) | Taken for a condition on Medical History? (MH Number) |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
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*[Implementation Note: "Medication Start Day" and "Medication End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact study days, categorize as follows:*

- > 1 month prior to enrollment

*If ongoing, display "Ongoing" in the "Medication End Day" column.*
*If taken for an AE or MH, display "Yes" with the AE or MH Number in parentheses, e.g., "Yes (7)".]*

## LISTING 16.2.11a:
## Pregnancy Reports - Adults

[Implementation Note: Only include the "Pregnancy Number" column if a participant has more than 1 pregnancy.
Date of Conception will be calculated based on estimated delivery date. BMI will be calculated based on pre-pregnancy height and weight.
Mother's weight gain will be calculated based on pre-pregnancy weight and end of pregnancy weight.
If a major congenital anomaly with previous pregnancy, display "Yes" and the text from the "specify" field, separated by a colon.
If any substance use is reported, include a listing of substance use.
If autopsy revealed an alternate etiology, display "Yes" and the text from the "specify" field, separated by a colon.
If abnormality in product of conception, display "Yes" and the text from the "specify" field, separated by a colon.]

### Table 1 – Maternal Information

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

### Table 2 – Gravida and Para

| | | | Live Births | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Participant ID | Pregnancy Number | Gravida | Extremely Preterm Births | Very Preterm Births | Early Preterm Births | Late Preterm Births | Early Term Births | Full Term Births | Late Term Births | Post Term Births | Still Births | Spontaneous Abortion/ Miscarriage | Elective Abortions | Therapeutic Abortions | Major Congenital Anomaly with Previous Pregnancy? |
| | | | | | | | | | | | | | | | |
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Note: Gravida includes the current pregnancy, para events do not.

## Table 3 – Live Birth Outcomes

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

## Table 4 – Still Birth Outcomes

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

## Table 5 – Spontaneous, Elective, or Therapeutic Abortion Outcomes

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