Statistical Analysis Plan

A Double Blind, Randomized, Placebo-Controlled, Phase 1 Dose Escalation Trial to Evaluate the Safety and Immunogenicity of an Inactivated Yellow Fever Virus Vaccine, HydroVax-002 YFV, in Healthy Adults

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10 February, 2023

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Protocol Number: 20-001
IND Sponsor: Najít Technologies, Inc. (NTI)
Version Number: 2.0

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STUDY OVERVIEW

Protocol Number Code:	**NTI Protocol: 20-001**
Development Phase:	Phase 1
Products:	HydroVax-002 YFV
Form/Route:	Intramuscular Injection
Indication Studied:	Yellow fever virus
Sponsor:	Najít Technologies, Inc.
Co-Principal Investigators:	[redacted]
Scientific Lead:	[redacted]
Clinical Program Manager:	[redacted]
Biostatistician:	[redacted]
Clinical Trial Initiation Date:	10Dec2021
Date of the Analysis Plan:	10Feb2023
Version Number:	2.0

This study was performed in compliance with Good Clinical Practice.

SIGNATURE PAGE

SPONSOR: Najít Technologies, Inc.

STUDY TITLE: A Double Blind, Randomized, Placebo-Controlled, Phase 1 Dose Escalation Trial to Evaluate the Safety and Immunogenicity of an Inactivated Yellow Fever Virus Vaccine, HydroVax-002 YFV, in Healthy Adults

PROTOCOL NUMBER: NTI 20-001

[redacted]

[redacted] Date: [redacted]

[redacted]

[redacted] Date: [redacted]

[redacted]

[redacted] Mark Slifka [redacted] Date: [redacted]

[redacted]

[redacted] Date: [redacted]

1. PREFACE

The Statistical Analysis Plan for "A Double Blind, Randomized, Placebo-Controlled, Phase 1 Dose Escalation Trial to Evaluate the Safety and Immunogenicity of an Inactivated Yellow Fever Virus Vaccine, HydroVax-002 YFV, in Healthy Adults" (NTI protocol 20-001) describes the analyses to be performed for the interim and final analyses defined in the complete clinical protocol.

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 analyses.

This document contains four major sections: (1) a review of the study design (Section 2, Section 3, Section 4), (2) sample size general statistical considerations (Section 5, Section 6), (3) comprehensive statistical analysis methods for safety and immunogenicity outcomes (Section 8, Section 9), and (4) a list of proposed tables and figures (Section 13). Any deviation from this analysis plan will be described and justified in the interim and final analysis reports, as appropriate. The reader of this analysis plan is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

2. INTRODUCTION

This trial is a randomized, placebo controlled, double-blind (within dosing group), dose escalation Phase 1 trial evaluating dosages of 1 mcg and 5 mcg of HydroVax-002 YFV vaccine given intramuscularly on Day 1 (the day of first vaccination is defined as Day 1) and Day 29 in healthy adults ≥18 and <50 years of age. The study consists of two dosing groups of HydroVax-002 YFV vaccine to be enrolled sequentially. Each dose group will consist of 10 individuals who receive HydroVax-002 YFV and 2 or 3 who receive placebo. The initial dose of HydroVax-002 YFV to be evaluated in Group 1 is 1 mcg and the next dose to be evaluated in Group 2 is 5 mcg. Following assessment of safety and reactogenicity data of Group 1 by the Safety Monitoring Committee (SMC), the vaccine dose was increased to 5 mcg for Group 2. An overview of the study design is provided in the complete clinical protocol.

2.1. Purpose of the Analyses

The protocol for NTI 20-001 calls for a planned interim analysis of safety, reactogenicity, and immune response data once all subjects have completed the Day 57 visit and the data are entered in the database, validated and monitored according to the clinical monitoring plan. This Statistical Analysis Plan encompasses both the planned interim analysis and final analysis. The goal of the interim analysis is to provide information for manuscript preparation. While the results will not be used to make any decisions concerning the conduct of this trial, they may be used to make decisions on activities external to this trial such as the design of future trials of this vaccine.

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives

Primary:

To assess the safety, reactogenicity, and tolerability of the HydroVax-002 YFV vaccine administered intramuscularly in a two-dose series on Days 1 and 29 at a dose of 1 mcg or a dose of 5 mcg

Secondary:

To assess YFV-specific neutralizing antibody responses after a first dose and after a second dose of HydroVax-002 YFV vaccine given at dose levels of 1 mcg and 5 mcg

Exploratory:

[redacted]

To assess long-term YFV-specific neutralizing antibody responses after a second dose of HydroVax-002 YFV vaccine given at dose levels of 1 mcg and 5 mcg

3.2. Endpoints

Primary Outcome Measures:

- Occurrence of all serious adverse events (SAEs) at any time during the study
- Occurrence of all Grade 3 unsolicited adverse events (AEs) from first vaccination through Day 29 after the second vaccination
- Occurrence of all Grade 3 laboratory toxicities from first vaccination through Day 15 after the second vaccination
- Occurrence of solicited local AE and reactogenicity signs and symptoms in the 7 days after each vaccination
- Occurrence of solicited systemic AE and reactogenicity signs and symptoms in the 7 days after each vaccination
- Occurrence of any AE through Day 29 after the second vaccination

Secondary Outcome Measures:

- Percentage of subjects achieving seroconversion (≥1:10 in plaque reduction neutralizing titer [$PRNT_{50}$] titer, at Day 29 after first vaccination and at Day 29 after second vaccination
- Geometric mean neutralizing titers at days 15 and 29 after first vaccination and at Days 15, 29, and 57 following second vaccination
- Reverse cumulative distribution curve of neutralizing titers on Days 15 and 29 after first vaccination and at Days 15, 29 and 57after the second vaccination for each dose group and for all dose groups combined

Exploratory Outcome Measures:

- Geometric mean neutralizing titers at Day 180 following second vaccination
- Reverse cumulative distribution curve of neutralizing titers on Day 180 after the second vaccination for each dose group and for all dose groups combined

3.3. Study Definitions and Derived Variables

Seroconversion is defined as a $PRNT_{50}$ neutralizing antibody titer of ≥1:10. The limit of detection in the neutralizing assay will be a titer of <10. For the purposes of determining seroconversion rates and GMT, antibody titers of <10 will be assumed to be 5 (one dilution step below the assay limit value).

For exploratory analysis using the LNI measurement the limit of detection will be defined as 0.70, and seroconversion is defined as an LNI value ≥ 0.70. For the purposes of determining seroconversion rates and GMT, LNI titers of <0.70 will be set to value of 0.35 (one-half the limit of detection).

4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

This trial will be a randomized, placebo controlled, double-blind (within dosing group), dose escalation Phase 1 trial evaluating dosages of 1 mcg and 5 mcg of HydroVax-002 YFV vaccine given intramuscularly on Day 1 (the day of first vaccination is defined as Day 1) and Day 29 in healthy adults ≥18 and <50 years of age. The study will consist of two dosing groups of HydroVax-002 YFV vaccine to be enrolled sequentially. Each dose group will consist of 10 individuals who receive HydroVax-002 YFV and 2 or 3 who receive placebo. The initial dose of HydroVax-002 YFV to be evaluated in Group 1 will be 1 mcg and the next dose to be evaluated in Group 2 will be 5 mcg. Following assessment of safety and reactogenicity data of Group 1 by the Safety Monitoring Committee (SMC), the vaccine dose will be increased to 5 mcg for Group 2. All participants will be monitored for local and systemic solicited adverse events for 7 days following each vaccination, unsolicited adverse events for 28 days following each vaccination, and for the occurrence of new onset chronic medical conditions and serious adverse events from the time of first vaccination until 6 months following the second vaccination. Safety laboratory tests will be performed prior to vaccination and at days 4 and 15 following vaccination. YFV neutralizing assays will be performed on blood samples collected prior to each vaccine, 15 days following each vaccine, and at days 29, 57, and 180 following the second dose of vaccine.

For each dosing group, the first four subjects enrolled (the sentinel subgroup) will include three HydroVax-002 YFV recipients and one placebo recipient. After the four subjects in the Group 1 sentinel subgroup are enrolled and given their first vaccination, enrollment will then be stopped pending a review of the clinical laboratory, reactogenicity, and safety data collected through the post vaccination Day 8 visit for the last of those subjects. This review may be conducted by an internal safety review committee (ISRC), consisting of the medical monitor, medical officer, clinical program manager, and the PI, or by the SMC, as indicated and detailed in complete clinical protocol. Approval by the reviewing group will allow administration of the second vaccination to the sentinel subgroup and continued enrollment of the remaining 9 Group 1 subjects (expanded group) to resume to complete enrollment of 13 participants (10 vaccine and 3 placebo).

After Group 1 enrollment is completed, enrollment will be stopped pending an SMC review of the clinical laboratory, reactogenicity, and adverse event information through the post 2nd vaccination Day 15 visit for all Group 1 subjects. Approval by the SMC will allow escalation to Group 2, and initiation of enrollment of the Group 2 sentinel subgroup. After the four subjects in the Group 2 sentinel subgroup are enrolled and given their first vaccination, enrollment will then be stopped pending a safety review of the sentinel subgroup as specified for the low dose cohort. Approval will allow administration of vaccination 2 to the sentinel subgroup and continued enrollment of Group 2 subjects (expanded group) to complete study enrollment.

This study will accrue 25 participants: (10 receiving 1 mcg of HydroVax-002 YFV; 10 receiving 5 mcg of HydroVax-002 YFV; and 5 receiving placebo).

The full schedule of events is provided in the complete clinical protocol.

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

For this Phase 1 first-in-human trial, a conservative dose escalation design will be used, in which each dose group of 10 vaccine recipients, and a total of 5 placebo recipients is split into two subgroups. The first subgroup, termed the sentinel subgroup, includes 3 vaccine and 1 placebo recipient. In each of the two (1 mcg and 5 mcg) dose phases, enrollment is halted after vaccination of the sentinel subgroup. This allows the opportunity to identify early vaccine related adverse events in this subgroup prior to exposure of additional

subjects, a design which decreases the risk of multiple serious vaccine related adverse events compared to sequential vaccination of the entire dose group without halting. After enrollment of the expanded subgroups, escalation to the next dose group will be delayed until 14 days of safety data following the second vaccination (corresponding to study Day 15) is available from all subjects in the preceding dose group.

Placebo recipients are included in order to maintain blinding, provide some safety reference data, and to provide controls for the immunogenicity assays.

4.3. Selection of Study Population

This is the first human trial of HydroVax-002 YFV, thus the study population is healthy individuals ages ≥18 and <50 years.

4.4. Treatments

[redacted]

4.4.1. Treatments Administered

4.4.1.1. Vaccine

The HydroVax-002 YFV vaccine is a yellow fever virus, Vero cell tissue culture-derived vaccine inactivated with hydrogen peroxide, formulated with 0.1% aluminum hydroxide. [redacted]

4.4.1.2. Placebo and Diluent

Sodium Chloride Injection USP, 0.9% (NaCl 0.9%, Normal Saline) will be used as the placebo and diluent.

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

Once consented and upon entry of demographic data and confirmation of eligibility for the trial, the subject will be assigned to a treatment arm within each dose group (low dose and high dose) subjects will be randomly assigned to receive the study test product or placebo. Subjects will be block randomized so that 1 of the first 4 sentinel subjects will receive placebo and the other 3 active vaccine. In the expanded groups, 7 of the 8 or 9 subjects will be randomized to vaccine and 1 or 2 to placebo. Subjects will receive the same treatment for both vaccinations

Enrollment of subjects will be done online using the enrollment module of Advantage eClinical®. The randomization code will be prepared by statisticians at the SDCC and included in the enrollment module for the trial. Advantage eClinical® will generate a treatment assignment for each subject after the demographic and eligibility data have been entered into the system. A designated individual at each site will be provided with a code list for emergency unblinding purposes, which will be kept in a secure place.

4.4.3. Blinding

This is a partially-blinded clinical trial.

Study staff and investigators will not be blinded to dose group but, within dose groups, subjects, investigators, and study staff other than unblinded site research pharmacist (or other designated unblinded personnel

administering study product) will be blinded as to the subject's treatment assignment (vaccine vs. placebo). Laboratory personnel performing antibody assays will be blinded to dose group and treatment assignment.

The randomization scheme will be generated by the SDCC and provided to unblinded study personnel (i.e., research pharmacists performing study vaccination preparations and unblinded study vaccine administrators) at the clinical site.

An unblinded site research pharmacist will prepare the study product and an unblinded research nurse will inject the study product per the randomization assignment. The pharmacist will conceal the contents of the syringe by wrapping the syringe barrel with an overlay, opaque tape, or other equivalent material. In addition, the subject will be asked to look away when the vaccine is being administered.

The unblinded site research pharmacist and unblinded research nurse will not be involved in study-related assessments or have subject contact for data collection following study vaccine administration.

4.5. Immunogenicity and Safety Variables

The secondary immunogenicity outcome measure, seroconversion, is defined in Section 3.3 above.

5. SAMPLE SIZE CONSIDERATIONS

A total of 25 subjects, age ≥18 and <50 years of age, will be enrolled, where 10 subjects will receive 1 mcg of HydroVax-002 YFV, 10 will receive 5 mcg of HydroVax-002 YFV, and 5 will receive placebo. The study will consist of two dosing groups of HydroVax-002 YFV vaccine to be dosed sequentially. The initial dose of HydroVax-002 YFV to be evaluated in Group 1 will be 1 mcg and the next dose to be evaluated in Group 2 will be 5 mcg. The first 4 subjects of each group (3 receiving HydroVax-002 YFV and 1 receiving placebo) will serve as a sentinel subgroup.

The sample size of 10 vaccinated subjects in each dosage group with 5 subjects that receive placebo is small given the early stage (Phase 1) of the product's development, thus the precision of estimate for AEs is limited. Rare adverse events are not demonstrable in a clinical study of this size, however the probabilities of observing one or more AEs given various true event rates and sample sizes are presented in complete clinical protocol. If there are adverse events associated with HydroVax-002 YFV in this population, this study will have approximately 80% power to observe at least one such event in a dosage group size of 10 if the true rate is 15%. Comparisons will primarily be made between each vaccine dose group and placebo.

If there are no observed adverse events among the 10 vaccinated subjects in a dosage group associated with the investigational product, the upper 95% exact confidence bound for the incidence of adverse events will be 30.8%.

This study is not powered to detect small to moderate individual or pair-wise differences in immunogenicity outcomes between treatments.

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, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. In general, all data will be listed, sorted by treatment and subject, and when appropriate by visit number within subject. All summary tables will be structured with a column for each treatment (HydroVax-002 YFV, Placebo) and will be annotated with the total population size relevant to that table/treatment, including any missing observations.

Multiple observations within specific visit period are accepted. In the case of multiple observations within a specific window, the assessment value that is closest to the scheduled visit window will be used in the analyses for the post-baseline records. For screening and baseline visits, the last assessment value will be used. All the recorded data will be listed. If observations have the same distance to the scheduled assessment, the latest one will be used.

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

6.2. Reporting Conventions

The mean, standard deviation, and other statistics will be reported to 1 decimal place greater than the original data. The minimum and maximum will use the same number of decimal places as the original data. Percentages will be reported to one decimal place. For all other estimators, the NEJM statistical reporting guidelines will be followed: results will be presented with no more precision than is of scientific value and is meaningful. For example, measures of association, such as odds ratios, will be reported to two or three significant digits. Results derived from models will be limited to the appropriate number of significant digits.

6.3. Timing of Analyses

Unblinded analyses of the primary and secondary safety, reactogenicity, and immunogenicity outcomes (Neutralization and viremia) and any supporting analyses of these outcomes will be performed once all subjects have completed the Day 57 post-dose 2 visit and the data are entered in the primary clinical database, validated and monitored according to the clinical monitoring plan. The results will be provided to the sponsor and PI for research planning purposes. Individual subject listings will not be generated at this point.

The remaining analyses, including generation of all individual subject listings, will be completed and the CSR generated after the last subject's last visit is completed, and the final clinical database, including all long-term safety follow-up data, is cleaned, monitored and locked.

6.4. Analysis Populations

A summary of all subjects excluded from the analyses will be provided.

6.4.1. Safety Population

The Safety Analysis population includes all eligible subjects who received at least one dose of study vaccine. In the case of mis-randomization subjects will be analyzed according to the study product actually received.

6.4.2. Full Analysis Population

The full analysis (FA) population will consist of all subjects who received any study product (including control) and for whom immunogenicity endpoint data are available. In the case of mis-randomization subjects will be analyzed according to the study product actually received. Separate populations for each assay and/or dose may be needed if the availability of a sample's data varies across assay or if a subject is only eligible for analyses for one of the doses. For sake of simplicity, immunogenicity tables and figures will use a single "Full Analysis Population" label, however special cases and/or considerations for exclusions from assay- or dose-specific summaries will be provided in footnotes.

6.4.3. Per Protocol Population

The per protocol (PP) population will consist of all subjects who received both doses of study vaccine, for whom immunogenicity endpoint data are available, and who did not have major protocol deviations, such as receipt of non-study vaccines during the time frame prohibited by the protocol or receipt of the second study vaccination substantially out of window. As with the FA population, immunogenicity tables and figures will use a single "Per Protocol Population" label, however special cases and/or considerations for exclusions from assay- or dose-specific summaries will be provided in footnotes.

6.5. Covariates and Subgroups

The protocol does not define any formal subgroup analyses (e.g., analysis based on age, sex, race/ethnicity or other demographic characteristics), and the study is not adequately powered to perform subgroup analyses.

6.6. Missing Data

Missing safety and/or immunogenicity data will not be imputed. No search for outliers will be performed. However, the logarithmic transform will be used as appropriate to improve the distributional properties of the immunogenicity data and reduce the impact of potential outliers.

6.7. Multiple Comparisons/Multiplicity

Since this is a Phase 1 study, the analyses are descriptive and so, neither formal testing nor any adjustments for multiple testing are planned. Since the early analyses of the primary and secondary outcomes are being performed for the sole purpose of planning other/future studies and will not impact the operations of this trial, no adjustments for early testing are planned.

7. STUDY SUBJECTS

7.1. Subject Disposition

A summary of subject screen failures will be presented (Table 1).

The composition of analysis populations, including reasons for subject exclusion, by treatment arm, will be presented (Table 2).

The disposition of subjects in the study will be tabulated by treatment group (Table 3). The table shows the total number of subjects screened, enrolled, receiving at least 1 dose, receiving at least 2 doses, discontinued dosing or terminated from study follow-up prior to the end of the study.

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

7.2. Protocol Deviations

A summary of protocol deviations will be presented by the reason for the deviation, the deviation category, and treatment group for all subjects (Table 4).

7.3. Demographic and Other Baseline Characteristics

Summaries of categorical and continuous demographics and baseline characteristics will be presented by treatment group (Table 5 and Table 6) and a demographic listing for all subjects will be presented (Listing 1). Ethnicity is categorized as Hispanic or Latino, or not Hispanic and not Latino. In accordance with NIH reporting policy, subjects may self-designate as belonging to more than one race or may refuse to identify a race, the latter reflected in the CRF as "No" to each racial option.

7.3.1. Concurrent Illnesses and Medical Conditions

All current illnesses and past pre-existing medical conditions will be MedDRA coded using MedDRA dictionary version 24.1 or higher. Summaries of subjects' pre-existing medical conditions will be presented by treatment group (Table 7).

7.3.2. Prior and Concurrent Medications

Summaries of medications that were started prior to dosing and continuing at the time of dosing will be presented by WHO Drug Terms 1 and 2 and treatment group (Table 8).

7.4. Measurements of Treatment Compliance

All subjects are intended to receive two doses of study product administered in the clinic. The dates of treatment by vaccination and treatment group will be provided (Listing 2). The number of subjects receiving one or two doses will be summarized in the previously described disposition table (Table 3).

8. SAFETY EVALUATION

The analyses of safety data will be primarily descriptive. Data will be represented to show difference in reactogenicity signs and symptoms and adverse events between the vaccine candidate and dose groups. Grading scales are provided in the clinical protocol.

8.1. Adverse Events

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

8.1.1. Solicited Events and Symptoms

Systemic solicited adverse events will be collected pre-vaccination, and systemic and local solicited adverse events will be collected 30 minutes post-vaccination and then daily for 7 days after each vaccination and graded on a scale of 0 (absent), 1 (mild), 2 (moderate) and 3 (severe). Systemic solicited symptoms will include feverishness, fatigue, headache, chills, nausea, new muscle pain (exclusive of the injection sites), aggravated muscle pain (increase of existing pain, exclusive of the injection site), new joint pain, and aggravated joint pain (increase of existing pain). Local events include: pain at injection site, tenderness at injection site, induration/swelling and erythema/redness. A summary of all recorded adverse events will be provided (Table 9). A subject-level summary of solicited events by symptom, severity and treatment group post-first, post-second or post-either dose will be presented (Table 10).

Analysis will also include the number and proportion of solicited systemic and local events over 7 days after each vaccination, as analyzed within each treatment group and after each vaccine administration (Table 11, Table 12, Table 13, Table 14, Table 15, Table 16, Table 17, Table 18, Table 19, Table 20, Table 21, and Table 22).

The maximum severity of solicited systemic and local events, organized by treatment group, will be summarized for each day post-vaccination (through day 7) in bar charts (Figure 2 , Figure 3, Figure 4 and Figure 5).

8.1.2. Unsolicited Adverse Events

The total number and proportion of subjects reporting unsolicited adverse event will be summarized by MedDRA system organ class and preferred term by severity and treatment group (Table 23). A subset analysis of related unsolicited adverse events will also be provided (Table 24). Unsolicited adverse events will also be summarized by time post-treatment for each treatment group (Table 25, Table 26, and Table 27).

Graphical representations will be provided for overall incidence of adverse events by MedDRA system organ class segregated by treatment group (Figure 6) and relationship to treatment (Figure 7), incidence of adverse events by severity (Figure 8) and incidence of adverse events by relationship to treatment (Figure 9).

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

A listing of all Serious Adverse Events will be provided (Listing 3).

A listing of non-serious, unsolicited, moderate or severe adverse events will be provided (Listing 4).

8.3. Pregnancies

For any subjects in the Safety population who became pregnant during the study, every attempt will be made to follow these subjects to completion of pregnancy to document the outcome, including information regarding any complications with pregnancy and/or delivery. The analysis will include information such as the total pregnancies, number of live births, and number of spontaneous abortions, elective abortions or still births by treatment will be presented (Listing 5, Listing 6, Listing 7, Listing 8, and Listing 9).

8.4. Clinical Laboratory Evaluations

The following laboratory measurements are collected and will be summarized:

- Hematology tests: White blood cell count, hemoglobin, platelets
- Blood chemistry tests: Sodium, potassium, bicarbonate, calcium, creatinine, glucose (non-fasting), ALT, AST, and total bilirubin.
- Urinalysis

Listings of abnormal laboratory results for hematology (Listing 10) chemistry (Listing 11) and urinalysis (Listing 12) will be provided.

The distribution of laboratory results by severity, study day and treatment group will be presented (Table 28). Abnormal laboratory results related to study treatment will be provided (Table 29).

8.5. Vital Signs and Physical Evaluations

Vital sign measurements include systolic blood pressure, diastolic blood pressure and oral temperature. Vital signs will be assessed at Day 1, 4, and 15 after each vaccination and through the end of the study if clinically indicated. A vital sign listing for all subjects will be provided (Listing 13) and a graphical representation of vital signs by assessment, maximum severity, study and treatment group will be presented (Figure 10).

9. IMMUNOGENICITY

9.1. Primary Analysis

As described in the complete clinical protocol, secondary immunogenicity endpoints will be measured using a standard plaque reduction neutralization assay ($PRNT_{50}$). A $PRNT_{50}$ assay uses a set amount of virus and serial dilutions of serum. The reciprocal of the last serum dilution that demonstrates ≥ 50% neutralization of the virus inoculum is defined as the $PRNT_{50}$ titer for that sample. The geometric mean $PRNT_{50}$ titer (GMT) and associated exact Blaker 95% confidence interval will be presented by treatment group at baseline Days 15 and 29 after the first vaccination and Days 15, 29, 57 and 180 after the second vaccination in both the FA (Table 30) and PP (Table 31) populations, as defined in Section 6.4.2. For each study day, the number of subjects in the FA or PP population with available immunogenicity data at the particular study day will be presented and used in calculations. A listing of all $PRNT_{50}$ and viremia results will be provided (Listing 14 and Listing 15). The reverse cumulative distribution of the $PRNT_{50}$ titer by Study Day and treatment group will also be generated for each vaccination in both FA and PP populations (Figure 11, Figure 12, and Figure 13).

9.2. Secondary and Exploratory Analysis

An alternative approach to assessing neutralizing titers is using a constant amount of serum and serial dilutions of the virus inoculum. This approach is referred to as a log-neutralizing index (LNI) and has been used in the past to assess immunogenicity following vaccination with YFV vaccine candidates. The log neutralizing index (LNI) and associated exact Blaker 95% confidence interval will be presented by treatment group at baseline Days 15 and 29 after the first vaccination and Days 15, 29, 57 and 180 after the second vaccination in both the FA (Table 30) and PP (Table 31) populations, as defined in Section 6.4.2. A listing of all LNI results will be provide (Listing 14). For each study day, the number of subjects in the FA or PP population with available immunogenicity data at the particular study day will be presented and used in calculations. The reverse cumulative distribution of the LNI titer by Study Day and treatment group will also be generated for each vaccination in both the FA and PP populations (Figure 15, Figure 16, Figure 17, and Figure 18).

The number of subjects seroconverting by either the LNI or $PRNT_{50}$ measurements will be enumerated in either the FA (Table 32) or PP (Table 33) populations.

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

Version 6.0 of the protocol relegated the Day 180 immunogenicity objectives/outcomes to exploratory objectives/outcomes. In addition, the originally planned interim analysis was removed. Instead, an early analysis of the primary and secondary outcomes (and supporting summaries/analyses) was added to the protocol. Version 2.0 of the SAP incorporated these changes in addition to adding a viremia listing (Listing 15) that was erroneously excluded from Version 1.0 and fixing minor typos throughout the document.

11. ABBREVIATIONS

Abbreviation	Definition
AE	Adverse event
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BMI	Body mass index
CI	Confidence interval
CRF	Case report form
DNA	Deoxyribonucleic acid
FA	Full analysis
GMT	Geometric mean titer
ID	Identification
LNI	Log neutralizing index
NIH	National Institutes of Health
NTI	Najít technologies, Inc.
PB	Preterm birth
PCR	Polymerase chain reaction
PFU	Plaque forming unit
PI	Principal investigator
PP	Per protocol
$PRNT_{50}$	Plaque reducing neutralization test 50% reduction
PT	Preferred term
SAE	Serious adverse event
SDCC	Statistical data coordinating center
SMC	Safety monitoring committee
SOC	System organ class
TB	Term birth
USP	United States Pharmacopeia
WHO	World Health Organization
YFV	Yellow fever virus

12. REFERENCES

1. Drummond R. CONSORT Revised: Improving the Reporting of Randomized Clinical Trials. JAMA. 2001; 285(15):2006-2007.

13. LISTING OF TABLES, FIGURES, AND LISTINGS

Table, figure, and listing shells are presented.

APPENDIX 1. TABLE MOCK-UPS

Table 1: Ineligibility Summary of Screen Failures

Category	Reason/Criterion	N	%
Screened		x	-
Screened but not enrolled		x	100
Eligible but not enrolled	Any Reason	x	xx
	[reason 1]	x	xx
	[reason 2]	x	xx
	…	…	…
Failing eligibility criteria	Any eligibility criterion[a]	x	xx
	Any inclusion criterion	x	xx
	[inclusion criterion 1]	x	xx
	[inclusion criterion 2]	x	xx
	…	…	…
	Any exclusion criterion	x	xx
	[exclusion criterion 1]	x	xx
	[exclusion criterion 2]	x	xx
	…	…	…

Denominator for percentages is the total number of subjects who were screened but not enrolled.
a: A subject could fail to meet more than one eligibility criterion. Thus, the sum of the counts of the individual reasons may add up to more than the total number of subjects who failed any eligibility criterion.

Table 2: Analysis Populations by Treatment Group

		HydroVax-002 YFV 1 mcg (N=XX)		HydroVax-002 YFV 5 mcg (N=XX)		Placebo (N=XX)		All Subjects (N=XX)	
Analysis Population	**Reason Subjects Excluded**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Safety Population	Included	x	x.x	x	x.x	x	x.x	x	x.x
	Excluded (Did not receive any vaccinations)	x	x.x	x	x.x	x	x.x	x	x.x
Post-Dose 1									
Full Analysis Population	Included	x	x.x	x	x.x	x	x.x	x	x.x
	Excluded	x	x.x	x	x.x	x	x.x	x	x.x
	Did not have pre- and post-baseline blood draws for YFV assay	x	x.x	x	x.x	x	x.x	x	x.x
	Did not receive any vaccinations	x	x.x	x	x.x	x	x.x	x	x.x
Per-Protocol Population	Included	x	x.x	x	x.x	x	x.x	x	x.x
	Excluded	x	x.x	x	x.x	x	x.x	x	x.x
	Did not receive any vaccinations	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
	[Insert other reasons, e.g. protocol deviation]	x	x.x	x	x.x	x	x.x	x	x.x
Post-Dose 2									
Full Analysis Population	Included	x	x.x	x	x.x	x	x.x	x	x.x
	Excluded	x	x.x	x	x.x	x	x.x	x	x.x
	Did not have pre- and post-baseline blood draws for YFV assay	x	x.x	x	x.x	x	x.x	x	x.x
	Did not receive any vaccinations	x	x.x	x	x.x	x	x.x	x	x.x
Per-Protocol Population	Included	x	x.x	x	x.x	x	x.x	x	x.x
	Excluded	x	x.x	x	x.x	x	x.x	x	x.x
	Did not receive any vaccinations	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
	[Insert other reasons, e.g. protocol deviation]	x	x.x	x	x.x	x	x.x	x	x.x

N = All enrolled subjects

Implementation Note: Above displays how dose-specific summaries will be presented if subject eligibilities differ by dose. Similar breakdowns by assay will be included if needed.

Table 3: Subject Disposition by Treatment Group

Subject Disposition	HydroVax-002 YFV 1 mcg (N=XX)		HydroVax-002 YFV 5 mcg (N=XX)		Placebo (N=XX)		All Subjects (N=XX)	
	n	%	n	%	n	%	n	%
Number of Subjects Screened	-	-	-	-	-	-	x	-
Number of Subjects Enrolled/Randomized	x	x.x	x	x.x	x	x.x	x	x.x
Number of Subjects Receiving First Vaccination	x	x.x	x	x.x	x	x.x	x	x.x
Number of Subjects Receiving Second Vaccination	x	x.x	x	x.x	x	x.x	x	x.x
Number of Subjects Terminating Early prior to Study Day 57 Post-Dose 2	x	x.x	x	x.x	x	x.x	x	x.x
Number of Subjects Terminating Early prior to Study Day 180 Post-Dose 2	x	x.x	x	x.x	x	x.x	x	x.x
Reasons for Early Discontinuation from the Study								
Enrolled But Treatment not Administered	x	x.x	x	x.x	x	x.x	x	x.x
Lost to Follow-up	x	x.x	x	x.x	x	x.x	x	x.x
Physician Decision	x	x.x	x	x.x	x	x.x	x	x.x
Withdrawal by Subject	x	x.x	x	x.x	x	x.x	x	x.x

Table 4: Distribution of Protocol Deviations by Category, Type, and Treatment Group

		HydroVax-002 YFV 1 mcg (N=xx)		HydroVax-002 YFV 5 mcg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
Category	**Deviation Type**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**	**# of Subj.**	**# of Dev.**
Eligibility/enrollment	Any type	x	x	x	x	x	x	x	x
	<Deviation Type 1>	x	x	x	x	x	x	x	x
Follow-up visit schedule	Any type	x	x	x	xx	x	xx	xx	xx
	Missed visit/visit not conducted	x	x	x	x	x	x	x	x
	Out of window visit	x	x	x	x	x	x	xx	xx
Protocol procedure/ assessment	Any type	x	x	x	x	x	x	x	x
	Required procedure done incorrectly	x	x	x	x	x	x	x	x
	Required procedure not conducted	x	x	x	x	x	x	x	x
	Specimen result not obtained	x	x	x	x	x	x	x	x
	Too few aliquots obtained	x	x	x	x	x	x	x	x
Treatment administration schedule	Any type	x	x	x	x	x	x	x	x
	Out of window visit	x	x	x	x	x	x	x	x
Blinding policy/procedure	Any type	x	x	x	x	x	x	x	x
	<Deviation Type 1>	x	x	x	x	x	x	x	x
Treatment administration	Any type	x	x	x	x	x	x	x	x
	<Deviation Type 1>	x	x	x	x	x	x	x	x

Table 5: Summary of Categorical Demographic and Baseline Characteristics by Treatment Group, All Enrolled Subjects

		HydroVax-002 YFV 1 mcg (N=XX)		HydroVax-002 YFV 5 mcg (N=XX)		Placebo (N=XX)		All Subjects (N=XX)	
Demographic Category	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Gender	Female	x	x.x	x	x.x	x	x.x	x	x.x
	Male	x	x.x	x	x.x	x	x.x	x	x.x
Ethnicity	Hispanic or Latino	x	x.x	x	x.x	x	x.x	x	x.x
	Not Hispanic or Latino	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x
	Unknown	x	x.x	x	x.x	x	x.x	x	x.x
Race	American Indian or Alaskan Native	x	x.x	x	x.x	x	x.x	x	x.x
	Asian	x	x.x	x	x.x	x	x.x	x	x.x
	Native Hawaiian or other Pacific Islander	x	x.x	x	x.x	x	x.x	x	x.x
	Black or African American	x	x.x	x	x.x	x	x.x	x	x.x
	White	x	x.x	x	x.x	x	x.x	x	x.x
	Multi-Racial	x	x.x	x	x.x	x	x.x	x	x.x
	Unknown	x	x.x	x	x.x	x	x.x	x	x.x

Table 6: Summary of Continuous Demographic and Baseline Characteristics by Treatment Group, All Enrolled Subjects

Variable	Statistic	HydroVax-002 YFV 1 mcg (N=XX)	HydroVax-002 YFV 5 mcg (N=XX)	Placebo (N=XX)	All Subjects (N=XX)
Age (years)	Mean	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x
	Minimum	x	x	x	x
	Maximum	x	x	x	x
Height (cm)	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x
Weight (kg)	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x
BMI (kg/m^2)	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x

Table 7: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA® System Organ Class and Treatment Arm

	HydroVax-002 YFV 1 mcg (N=xx)		HydroVax-002 YFV 5 mcg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
MedDRA® System Organ Class	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any SOC	x	x.x	x	x.x	x	x.x	x	x.x
[SOC 1]	x	x.x	x	x.x	x	x.x	x	x.x
[SOC 2]	x	x.x	x	x.x	x	x.x	x	x.x
…	x	x.x	x	x.x	x	x.x	x	x.x

N=All enrolled subjects
n = Number of subjects reporting medical history within the specified SOC. A subject is only counted once per SOC.

Table 8: Summary of Concomitant Medications

		HydroVax-002 YFV 1 mcg (N=XX)		HydroVax-002 YFV 5 mcg (N=XX)		Placebo (N=XX)		All Subjects (N=XX)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Level 1 Codes	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
Alimentary Tract And Metabolism	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antidiarrheals, Intestinal Anti-inflammatory/Antiinfective Agents	x	x.x	x	x.x	x	x.x	x	x.x
	Antiemetics And Antinauseants	x	x.x	x	x.x	x	x.x	x	x.x
	Drugs For Acid Related Disorders	x	x.x	x	x.x	x	x.x	x	x.x
	Drugs For Functional Gastrointestinal Disorders	x	x.x	x	x.x	x	x.x	x	x.x
	Mineral Supplements	x	x.x	x	x.x	x	x.x	x	x.x
	Vitamins	x	x.x	x	x.x	x	x.x	x	x.x
Anti-infective For Systemic Use	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antibacterials For Systemic Use	x	x.x	x	x.x	x	x.x	x	x.x
	Vaccines	x	x.x	x	x.x	x	x.x	x	x.x
Blood And Blood Forming Organs	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antianemic Preparations	x	x.x	x	x.x	x	x.x	x	x.x
	Antithrombotic Agents	x	x.x	x	x.x	x	x.x	x	x.x
Cardiovascular System	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Diuretics	x	x.x	x	x.x	x	x.x	x	x.x
Dermatologicals	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antibiotics And Chemotherapeutics For Dermatological Use	x	x.x	x	x.x	x	x.x	x	x.x
	Antifungals For Dermatological Use	x	x.x	x	x.x	x	x.x	x	x.x
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	x	x.x	x	x.x	x	x.x	x	x.x
	Corticosteroids, Dermatological Preparations	x	x.x	x	x.x	x	x.x	x	x.x
	Emollients And Protectives	x	x.x	x	x.x	x	x.x	x	x.x

		HydroVax-002 YFV 1 mcg (N=XX)		HydroVax-002 YFV 5 mcg (N=XX)		Placebo (N=XX)		All Subjects (N=XX)	
WHO Drug Code Level 1, Anatomic Group	**WHO Drug Code Level 2, Therapeutic Group**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Other Dermatological Preparations	x	x.x	x	x.x	x	x.x	x	x.x
Genito Urinary System And Sex Hormones	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Other Gynecologicals	x	x.x	x	x.x	x	x.x	x	x.x
	Sex Hormones And Modulators Of The Genital System	x	x.x	x	x.x	x	x.x	x	x.x
	Urologicals	x	x.x	x	x.x	x	x.x	x	x.x
Musculo-Skeletal System	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antiinflammatory And Antirheumatic Products	x	x.x	x	x.x	x	x.x	x	x.x
Nervous System	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Analgesics	x	x.x	x	x.x	x	x.x	x	x.x
	Antiepileptics	x	x.x	x	x.x	x	x.x	x	x.x
	Psychoanaleptics	x	x.x	x	x.x	x	x.x	x	x.x
	Psycholeptics	x	x.x	x	x.x	x	x.x	x	x.x
Respiratory System	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Antihistamines For Systemic Use	x	x.x	x	x.x	x	x.x	x	x.x
	Cough And Cold Preparations	x	x.x	x	x.x	x	x.x	x	x.x
	Drugs For Obstructive Airway Diseases	x	x.x	x	x.x	x	x.x	x	x.x
	Nasal Preparations	x	x.x	x	x.x	x	x.x	x	x.x
Sensory Organs	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	Ophthalmologicals	x	x.x	x	x.x	x	x.x	x	x.x
Various	**Any Level 2 Codes**	x	x.x	x	x.x	x	x.x	x	x.x
	General Nutrients	x	x.x	x	x.x	x	x.x	x	x.x
	Unspecified Herbal And Traditional Medicine	x	x.x	x	x.x	x	x.x	x	x.x

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

Table 9: Summary of Adverse Events – Safety Population

Subjects[a] with	HydroVax-002 YFV 1 mcg (N = xx)		HydroVax-002 YFV 5 mcg (N = xx)		Placebo (N = xx)	
	n	%	n	%	n	%
At least one local solicited adverse event	x	x	x	x	x	x
At least one systemic solicited adverse event	x	x	x	x	x	x
At least one unsolicited adverse event	x	x	x	x	x	x
At least one related unsolicited adverse event	x	x	x	x	x	x
Mild (Grade 1)	x	x	x	x	x	x
Moderate (Grade 2)	x	x	x	x	x	x
Severe (Grade 3)	x	x	x	x	x	x
At least one severe (Grade 3) unsolicited adverse event	x	x	x	x	x	x
Related	x	x	x	x	x	x
Unrelated	x	x	x	x	x	x
At least one laboratory toxicity	x	x	x	x	x	x
At least one related laboratory toxicity	x	x	x	x	x	x
Mild (Grade 1)	x	x	x	x	x	x
Moderate (Grade 2)	x	x	x	x	x	x
Severe (Grade 3)	x	x	x	x	x	x
At least one severe (Grade 3) laboratory toxicity	x	x	x	x	x	x
Related	x	x	x	x	x	x
Unrelated	x	x	x	x	x	x
At least one serious adverse event[b]	x	x	x	x	x	x
At least one related, serious adverse event	x	x	x	x	x	x
At least one adverse event leading to early termination[c]	x	x	x	x	x	x

N = Number of subjects in the Safety Population and is the denominator for percentages
a: Subjects are counted once for each main category (i.e., non-indented row) regardless of the number of events. Subjects may be counted in more than one main category.
b: A listing of Serious Adverse Events is included in the Serious Adverse Event Listing.
c: As reported on the Adverse Event eCRF.

Table 10: Subject-Level Summary of Solicited Events by Symptom, Severity, Dose, and Treatment Group – Safety Population

Symptom	Severity	Post-Dose 1									Post-Dose 2									Post-Either Dose								
		HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)			HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)			HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
	Any Symptom																											
Any Symptom	None	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x
	Any Severity																											
	Mild																											
	Moderate																											
	Severe																											
	Any Systemic Symptom																											
[Systemic Symptom 1]	None																											
	Any Severity																											
	Mild																											
	Moderate																											
	Severe																											
[Systemic Symptom 2]	None																											
	Any Severity																											
	Mild																											
	Moderate																											
	Severe																											

Symptom	Severity	Post-Dose 1									Post-Dose 2									Post-Either Dose								
		HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)			HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)			HydroVax-002 YFV 1 mcg (N = xx)			HydroVax-002 YFV 5 mcg (N = xx)			Placebo (N = xx)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Any Local Symptom																												
[Local Symptom 1]	None																											
	Any Severity																											
	Mild																											
	Moderate																											
	Severe																											
[Local Symptom 2]	None																											
	Any Severity																											
	Mild																											
	Moderate																											
	Severe																											

N = Number of subjects in the Safety Population with solicited event data available for the specified time period and is the denominators for percentages.
The Any Symptom counts classify each subject by the maximum severity reported for the category; each subject is only counted once.

Table 11: Number and Percentage of Subjects Experiencing Systemic Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – HydroVax-002 YFV, 1 mcg

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 12: Number and Percentage of Subjects Experiencing Systemic Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – HydroVax-002 YFV, 5 mcg

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 13: Number and Percentage of Subjects Experiencing Solicited Systemic Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – Placebo

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 14: Number and Percentage of Subjects Experiencing Systemic Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – HydroVax-002 YFV, 1 mcg

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 15: Number and Percentage of Subjects Experiencing Systemic Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – HydroVax-002 YFV, 5 mcg

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 16: Number and Percentage of Subjects Experiencing Systemic Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – Placebo

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Systemic Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Elevated Oral Temperature	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Feverishness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Fatigue	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Headache	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Chills	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Nausea	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Aggravated muscle pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
New joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Aggravated joint pain	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 17: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – HydroVax-002 YFV, 1 mcg

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Redness Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling (functional grade)	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 18: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – HydroVax-002 YFV, 5 mcg

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Redness Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling (functional grade)	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 19: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 1 – Placebo

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Redness Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling (functional grade)	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 20: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – HydroVax-002 YFV, 1 mcg

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 1 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Rmedness Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling (functional grade)	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Table 21: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – HydroVax-002 YFV, 5 mcg

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV - 5 mcg, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Induration/Swelling Measurement	None	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Mild	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Moderate	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Severe	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Not Reported	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
Erythema/Redness Measurement	None	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Mild	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Moderate	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Severe	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Not Reported	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
Induration/Swelling (functional grade)	None	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Mild	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Moderate	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Severe	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X
	Not Reported	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X	X	X.X

Table 22: Number and Percentage of Subjects Experiencing Local Solicited Events by Symptom, Severity, Day Post Dosing, and Treatment Group – Post-Dose 2 – Placebo

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	Severity	n	%	n	%	n	%	n	%	n	%	n	%
Any Local Symptoms	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Pain at injection site	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Tenderness	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

Placebo, N=XX													
		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5-7	
Symptom	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Erythema/Redness Measurement	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
Induration/Swelling (functional grade)	None	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Mild	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Moderate	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Severe	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x
	Not Reported	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x	x	x.x

N = Number of subjects in the Safety Analysis Population who received the specified dose. Severity is the maximum severity reported post dosing for each subject for each day or interval.

Table 23: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Severity, and Treatment Group – Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Severity	HydroVax-002 YFV 1 mcg (N = xx)				HydroVax-002 YFV 5 mcg (N = xx)				Placebo (N = xx)			
			n	%	95% CI	m	n	%	95% CI	m	n	%	95% CI	m
Any SOC	Any PT	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
SOC 1	Any PT	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
	PT 1	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx

N = Number of subjects in the Safety Population and specified treatment group and is the denominator for all percentages.
n = Number of subjects with an event.
m = Total number of events (including multiple events within a subject).
95% CI is the [insert type of interval/method used to calculate interval].
For severity, a subject is counted once per preferred term and is summarized according to their highest severity within the SOC/PT.

Table 24: Related Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Severity, and Treatment Group – Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Severity	HydroVax-002 YFV 1 mcg (N = xx)				HydroVax-002 YFV 5 mcg (N = xx)				Placebo (N = xx)			
			n	%	95% CI	m	n	%	95% CI	m	n	%	95% CI	m
Any SOC	Any PT	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
SOC 1	Any PT	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
	PT 1	Any Severity	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Mild	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Moderate	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx
		Severe	x	xx	xx, xx	xx	x	xx	xx, xx	xx	x	xx	xx, xx	xx

N = Number of subjects in the Safety Population and specified treatment group and is the denominator for all percentages.
n = Number of subjects with an event.
m = Total number of events (including multiple events within a subject).
95% CI is the [insert type of interval/method used to calculate interval].
For severity, a subject is counted once per preferred term and is summarized according to their highest severity within the SOC/PT.

Table 25: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Day Post Dosing, and Treatment Group – HydroVax-002 YFV, 1 mcg

HydroVax-002 YFV -1 mcg (N=XX)									
MedDRA® System Organ Class	MedDRA® Preferred Term	Day 1-15 Post-Dose 1 (N=XX)		Day 16-29 Post-Dose 1 (N=XX)		Day 1-15 Post-Dose 2 (N=XX)		Day 16-57 Post-Dose 2 (N=XX)	
		n	%	n	%	n	%	n	%
Any SOC	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
Gastrointestinal Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Abdominal Pain Upper	x	x.x	x	x.x	x	x.x	x	x.x
	Diarrhoea	x	x.x	x	x.x	x	x.x	x	x.x
	Nausea	x	x.x	x	x.x	x	x.x	x	x.x
General Disorders And Administration Site Conditions	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Injection Site Pruritus	x	x.x	x	x.x	x	x.x	x	x.x
Infections And Infestations	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Upper Respiratory Tract Infection	x	x.x	x	x.x	x	x.x	x	x.x
	Urinary Tract Infection	x	x.x	x	x.x	x	x.x	x	x.x
Injury, Poisoning And Procedural Complications	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Contusion	x	x.x	x	x.x	x	x.x	x	x.x
	Skin Abrasion	x	x.x	x	x.x	x	x.x	x	x.x
	Thermal Burn	x	x.x	x	x.x	x	x.x	x	x.x
Investigations	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Blood Pressure Increased	x	x.x	x	x.x	x	x.x	x	x.x
	Urine Leukocyte Esterase	x	x.x	x	x.x	x	x.x	x	x.x
Musculoskeletal And Connective Tissue Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Rhabdomyolysis	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV -1 mcg (N=XX)									
MedDRA® System Organ Class	**MedDRA® Preferred Term**	**Day 1-15 Post-Dose 1 (N=XX)**		**Day 16-29 Post-Dose 1 (N=XX)**		**Day 1-15 Post-Dose 2 (N=XX)**		**Day 16-57 Post-Dose 2 (N=XX)**	
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Nervous System Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Headache	x	x.x	x	x.x	x	x.x	x	x.x
	Sinus Headache	x	x.x	x	x.x	x	x.x	x	x.x
Psychiatric Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Anxiety	x	x.x	x	x.x	x	x.x	x	x.x
Renal And Urinary Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Dysuria	x	x.x	x	x.x	x	x.x	x	x.x
Respiratory, Thoracic And Mediastinal Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Nasal Congestion	x	x.x	x	x.x	x	x.x	x	x.x
	Oropharyngeal Pain	x	x.x	x	x.x	x	x.x	x	x.x
Skin And Subcutaneous Tissue Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Dermatitis	x	x.x	x	x.x	x	x.x	x	x.x
	Rash	x	x.x	x	x.x	x	x.x	x	x.x

N = Number of subjects in the Safety Analysis Population. This table presents number and percentage of subjects. For each time period, a subject is only counted once per PT.

Table 26: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Day Post Dosing, and Treatment Group – HydroVax-002 YFV, 5 mcg

HydroVax-002 YFV -5 mcg (N=XX)									
MedDRA® System Organ Class	MedDRA® Preferred Term	Day 1-15 Post-Dose 1 (N=XX)		Day 16-29 Post-Dose 1 (N=XX)		Day 1-15 Post-Dose 2 (N=XX)		Day 16-57 Post-Dose 2 (N=XX)	
		n	%	n	%	n	%	n	%
Any SOC	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
Gastrointestinal Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Abdominal Pain	x	x.x	x	x.x	x	x.x	x	x.x
	Diarrhoea	x	x.x	x	x.x	x	x.x	x	x.x
	Vomiting	x	x.x	x	x.x	x	x.x	x	x.x
General Disorders And Administration Site Conditions	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Injection Site Bruising	x	x.x	x	x.x	x	x.x	x	x.x
Infections And Infestations	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Upper Respiratory Tract Infection	x	x.x	x	x.x	x	x.x	x	x.x
Injury, Poisoning And Procedural Complications	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Ligament Sprain	x	x.x	x	x.x	x	x.x	x	x.x
	Muscle Strain	x	x.x	x	x.x	x	x.x	x	x.x
Investigations	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Electrocardiogram Qrs Complex Prolonged	x	x.x	x	x.x	x	x.x	x	x.x
Musculoskeletal And Connective Tissue Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Flank Pain	x	x.x	x	x.x	x	x.x	x	x.x
	Rotator Cuff Syndrome	x	x.x	x	x.x	x	x.x	x	x.x

HydroVax-002 YFV -5 mcg (N=XX)									
MedDRA® System Organ Class	**MedDRA® Preferred Term**	**Day 1-15 Post-Dose 1 (N=XX)**		**Day 16-29 Post-Dose 1 (N=XX)**		**Day 1-15 Post-Dose 2 (N=XX)**		**Day 16-57 Post-Dose 2 (N=XX)**	
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Nervous System Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Presyncope	x	x.x	x	x.x	x	x.x	x	x.x
	Syncope	x	x.x	x	x.x	x	x.x	x	x.x
	Tension Headache	x	x.x	x	x.x	x	x.x	x	x.x
Respiratory, Thoracic And Mediastinal Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Oropharyngeal Pain	x	x.x	x	x.x	x	x.x	x	x.x
Vascular Disorders	**Any PT**	x	x.x	x	x.x	x	x.x	x	x.x
	Flushing	x	x.x	x	x.x	x	x.x	x	x.x

N = Number of subjects in the Safety Analysis Population. This table presents number and percentage of subjects. For each time period, a subject is only counted once per PT.

Table 27: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Day Post Dosing, and Treatment Group – Placebo

Placebo (N=XX)									
MedDRA® System Organ Class	MedDRA® Preferred Term	Day 1-15 Post-Dose 1 (N=XX)		Day 16-29 Post-Dose 1 (N=XX)		Day 1-15 Post-Dose 2 (N=XX)		Day 16-57 Post-Dose 2 (N=XX)	
		n	%	n	%	n	%	n	%
Any SOC	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
Gastrointestinal Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Toothache	x	x.x	x	x.x	x	x.x	x	x.x
Infections and Infestations	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Upper Respiratory Tract Infection	x	x.x	x	x.x	x	x.x	x	x.x
	Urinary Tract Infection	x	x.x	x	x.x	x	x.x	x	x.x
Injury, Poisoning and Procedural Complications	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Arthropod Bite	x	x.x	x	x.x	x	x.x	x	x.x
Metabolism and Nutrition Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Hypoglycaemia	x	x.x	x	x.x	x	x.x	x	x.x
Musculoskeletal and Connective Tissue Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Back Pain	x	x.x	x	x.x	x	x.x	x	x.x
	Musculoskeletal Stiffness	x	x.x	x	x.x	x	x.x	x	x.x
Nervous System Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Dizziness	x	x.x	x	x.x	x	x.x	x	x.x
	Paraesthesia	x	x.x	x	x.x	x	x.x	x	x.x
Respiratory, Thoracic And Mediastinal Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Respiratory Tract Congestion	x	x.x	x	x.x	x	x.x	x	x.x
Skin And Subcutaneous Tissue Disorders	Any PT	x	x.x	x	x.x	x	x.x	x	x.x
	Pseudofolliculitis Barbae	x	x.x	x	x.x	x	x.x	x	x.x
	Rash	x	x.x	x	x.x	x	x.x	x	x.x

N = Number of subjects in the Safety Analysis Population This table presents number and percentage of subjects. For each time period, a subject is only counted once per PT.

Table 28: Laboratory Results Maximum Severity, Study Day, Treatment Group and Parameter - Any Parameter

				None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Parameter	**Time Point**	**Treatment Group**	**N**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
[Parameter 1]	Baseline	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Day 4 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Day 15 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Day 29 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Day 4 Post-Dose 2	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Day 15 Post-Dose 2	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
	Max Severity Post Baseline	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x	x	x.x
Repeat for all laboratory parameters…											

The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety population with available laboratory results.

Implementation note: This table will be repeated for all hematology, blood chemistry and urinalysis parameters.

Table 29: Abnormal Laboratory Results Related to Study Treatment by Parameter, Maximum Severity, Study Day, Treatment Group and Parameter – Any Parameter

				Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3	
Parameter	**Time Point**	**Treatment Group**	**N**	**n**	**%**	**n**	**%**	**n**	**%**
[Parameter 1]	Day 4 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
	Day 15 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
	Day 29 Post-Dose 1	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
	Day 4 Post-Dose 2	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
	Day 15 Post-Dose 2	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
	Max Severity Post Baseline	HydroVax-002 YFV -1 mcg	XX	x	x.x	x	x.x	x	x.x
		HydroVax-002 YFV -5 mcg	XX	x	x.x	x	x.x	x	x.x
		Placebo	XX	x	x.x	x	x.x	x	x.x
Repeat for all laboratory parameters…									

The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.
N = Number of subjects in the Safety population with available laboratory results.

Implementation note: This table will be repeated for all hematology, blood chemistry and urinalysis parameters.

Table 30: $PRNT_{50}$ Geometric Mean Titer (GMT) and Log Neutralizing Titer Index (LNI) Results with 95% Confidence Intervals by Study Day and Treatment Group, Full Analysis Population

	HydroVax-002 YFV 1 mcg			HydroVax-002 YFV 5 mcg			Placebo		
Visit	**N**	**GMT**	**95% CI**	**N**	**GMT**	**95% CI**	**N**	**GMT**	**95% CI**
$PRNT_{50}$									
Day 1 (pre-vaccination)	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 57 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 180 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
LNI									
Day 1 (pre-vaccination)	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 57 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 180 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx

Table 31: $PRNT_{50}$ Geometric Mean Titer (GMT) and Log Neutralizing Titer Index (LNI) Results with 95% Confidence Intervals by Study Day and Treatment Group, Per Protocol Population

	HydroVax-002 YFV 1 mcg			HydroVax-002 YFV 5 mcg			Placebo		
Visit	**N**	**GMT**	**95% CI**	**N**	**GMT**	**95% CI**	**N**	**GMT**	**95% CI**
$PRNT_{50}$									
Day 1 (pre-vaccination)	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 57 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 180 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
LNI									
Day 1 (pre-vaccination)	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 1	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 15 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 29 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 57 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx
Day 180 Post-Dose 2	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx	xx	x.xx	x.xx, x.xx

Table 32: Number of Subjects Seroconverting for LNI Compared to $PRNT_{50}$ by Dose, Full Analysis Population

		$PRNT_{50}$					
		Seroconversion			No Seroconversion		
Population	Status by LNI	N	%	95% CI	N	%	95% CI
Day 29 Post-Dose 1	Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
	No Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
Day 57 Post-Dose 2	Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
	No Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x

Table 33: Number of Subjects Seroconverting for LNI Compared to $PRNT_{50}$ by Dose, Per-Protocol Population

		$PRNT_{50}$					
		Seroconversion			No Seroconversion		
Population	Status by LNI	N	%	95% CI	N	%	95% CI
Day 29 Post-Dose 1	Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
	No Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
Day 57 Post-Dose 2	Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x
	No Seroconversion	x	x.x	x.x, x.x	x	x.x	x.x, x.x

APPENDIX 2. LISTING MOCK-UPS

Listing 1: Demographic Data

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

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 2: Dates of Treatment by Vaccination and Treatment Group

Vaccination Number	Date Range	HydroVax-002 YFV 1 mcg (N=XX)	HydroVax-002 YFV 5 mcg (N=XX)	Placebo (N=XX)	All Subjects (N=XX)
01	Any Date Range	x	x	x	x
	DDMONYYYY - DDMONYYY	x	x	x	x
	…				
02	Any Date Range	x	x	x	x
	DDMONYYYY - DDMONYYY	x	x	x	x
	…				

Implementation Note: Meaningful date ranges will be selected based on the observed administration dates and their distribution.

Listing 3: Listing of Serious Adverse Events

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

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 4: Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events

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

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 5: Pregnancy Reports – Maternal Information

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

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 6: Pregnancy Reports – Gravida and Para

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

[a] Preterm Birth
[b] Term Birth

Implementation note: Sort order will be Subject ID

Listing 7: Pregnancy Reports – Live Birth Outcomes

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

Implementation note: Sort order will be Subject ID

Listing 8: Pregnancy Reports – Still Birth Outcomes

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

Implementation note: Sort order will be Subject ID

Listing 9: Pregnancy Reports – Spontaneous, Elective, or Therapeutic Abortion Outcomes

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

Listing 10: Listing of Abnormal Laboratory Results – Hematology

Hematology											
Treatment Group	Subject ID	Sex	Age (years)	Planned Study Day	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to Result?
XXX	XXX.XXX		XX								

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 11: Listing of Abnormal Laboratory Results – Chemistry

Chemistry											
Treatment Group	Subject ID	Sex	Age (years)	Planned Study Day	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to Result?
XXX	XXX.XXX		XX								

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 12: Listing of Abnormal Laboratory Results – Urinalysis

Urinalysis											
Treatment Group	**Subject ID**	**Sex**	**Age (years)**	**Planned Study Day**	**Actual Study Day**	**Laboratory Parameter (Units)**	**Result (Severity)**	**Relationship to Treatment**	**If Not Related, Alternative Etiology**	**Action Taken with Study Treatment**	**Subject Discontinued Due to Result?**
XXX	XXX.XXX		XX								

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 13: Vital Signs

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

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 14: Individual Immunogenicity Antibody Response Data for $PRNT_{50}$ and LNI Titers

Treatment Group	Subject ID	Visit Number	Study Day	$PRNT_{50}$ Titer	LNI Titer
XXX	XXX.XXX				

Implementation note: Sort order will be Treatment Group (Low Dose, High Dose, Placebo), Subject ID

Listing 15: Individual Viremia Data

Treatment Group	Subject ID	Visit Number	Study Day	Result
XXX	XXX.XXX			

APPENDIX 3. FIGURE MOCK-UPS

Figure 1: CONSORT Flow Diagram All Subjects

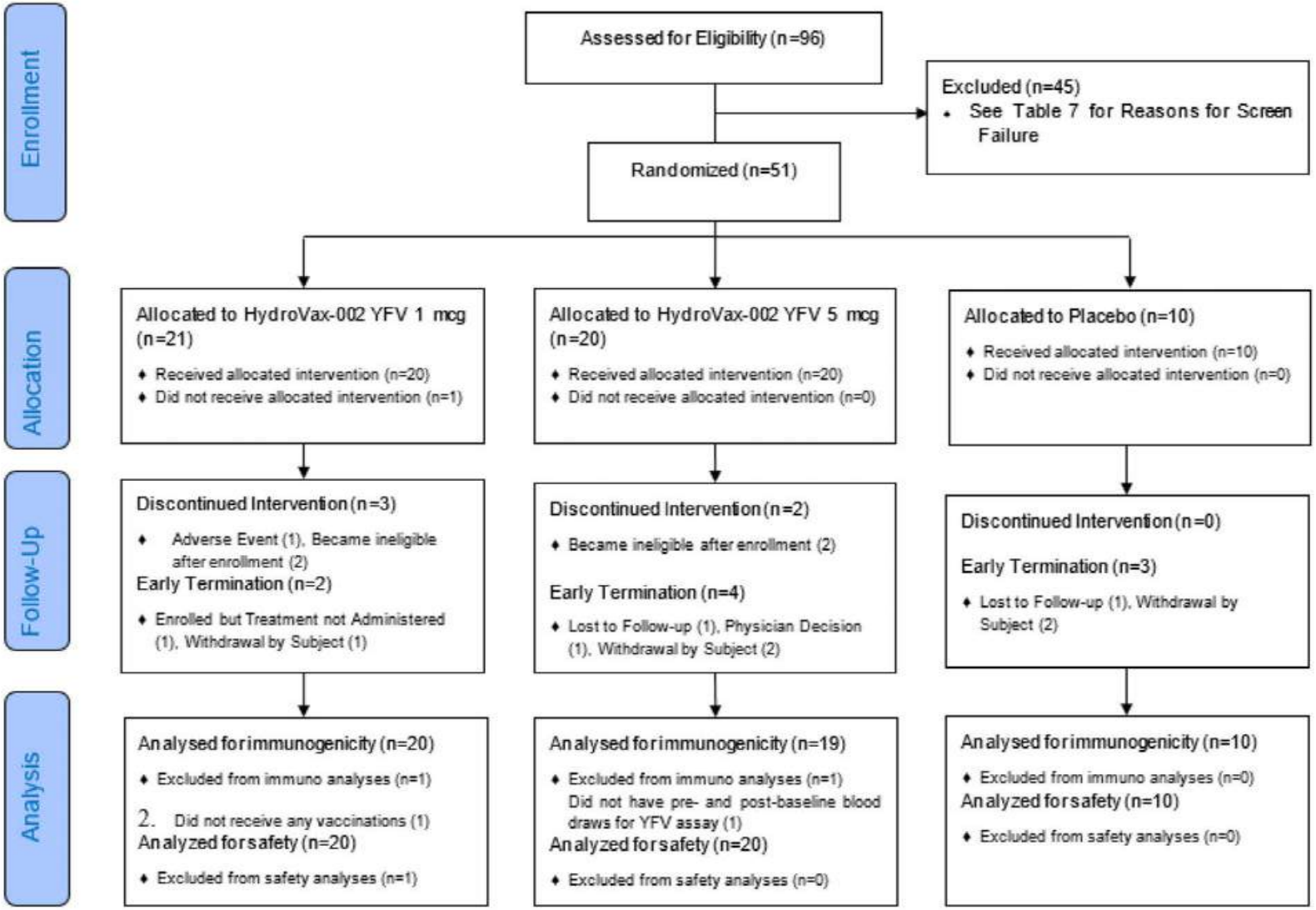
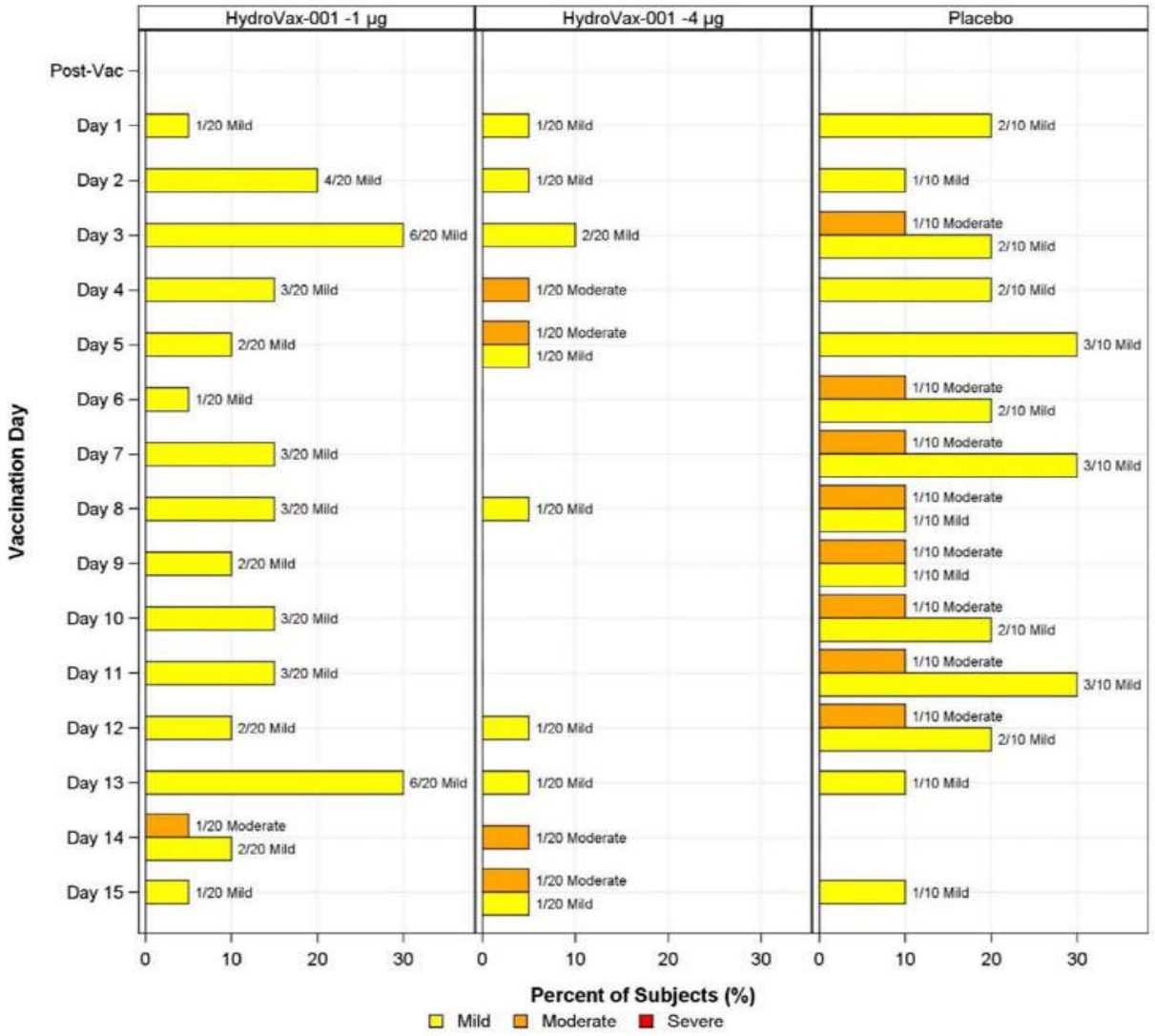
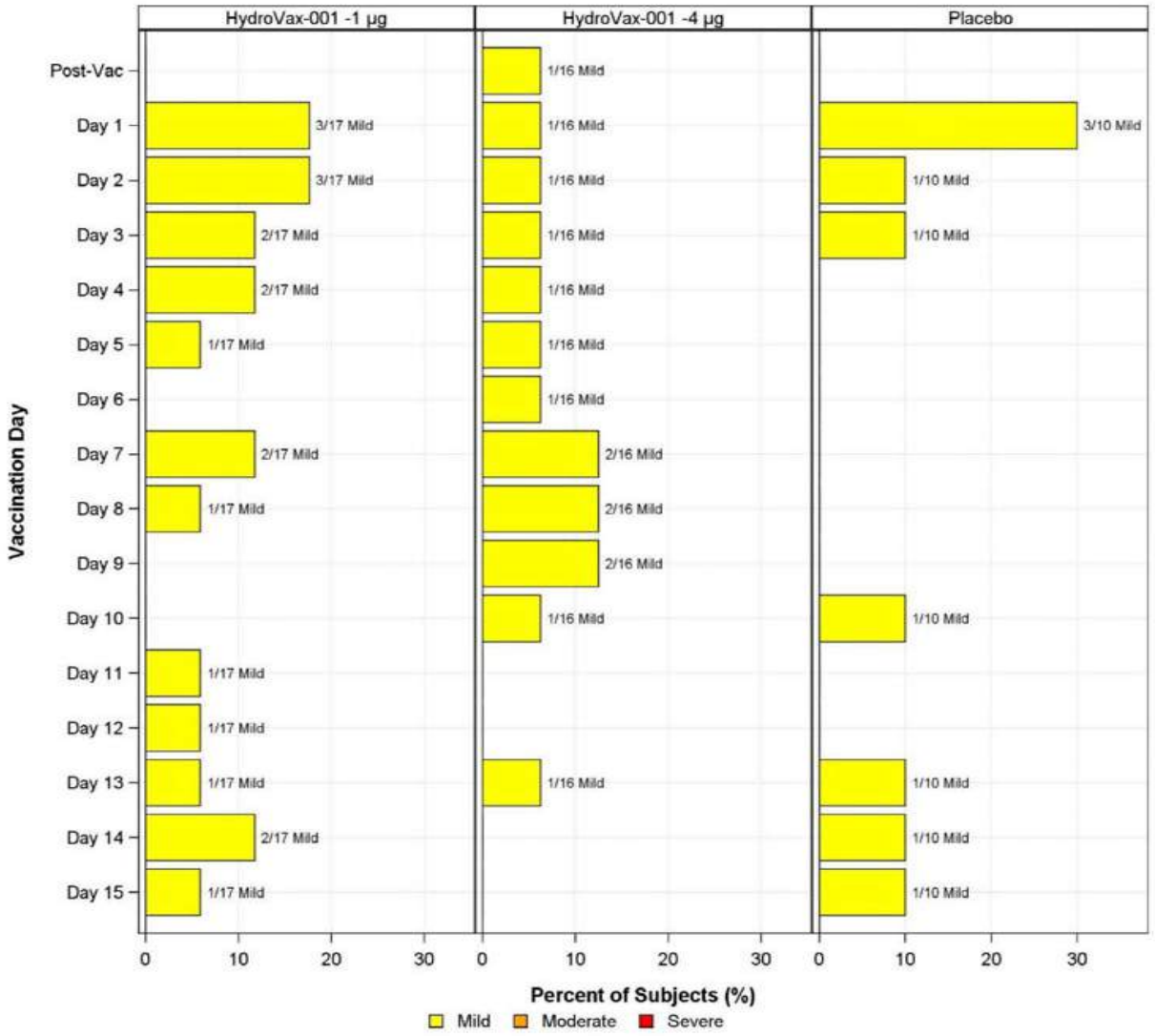


Figure 2: Maximum Severity of Solicited Systemic Symptoms per Subject by Day Post Treatment - Post-Dose 1



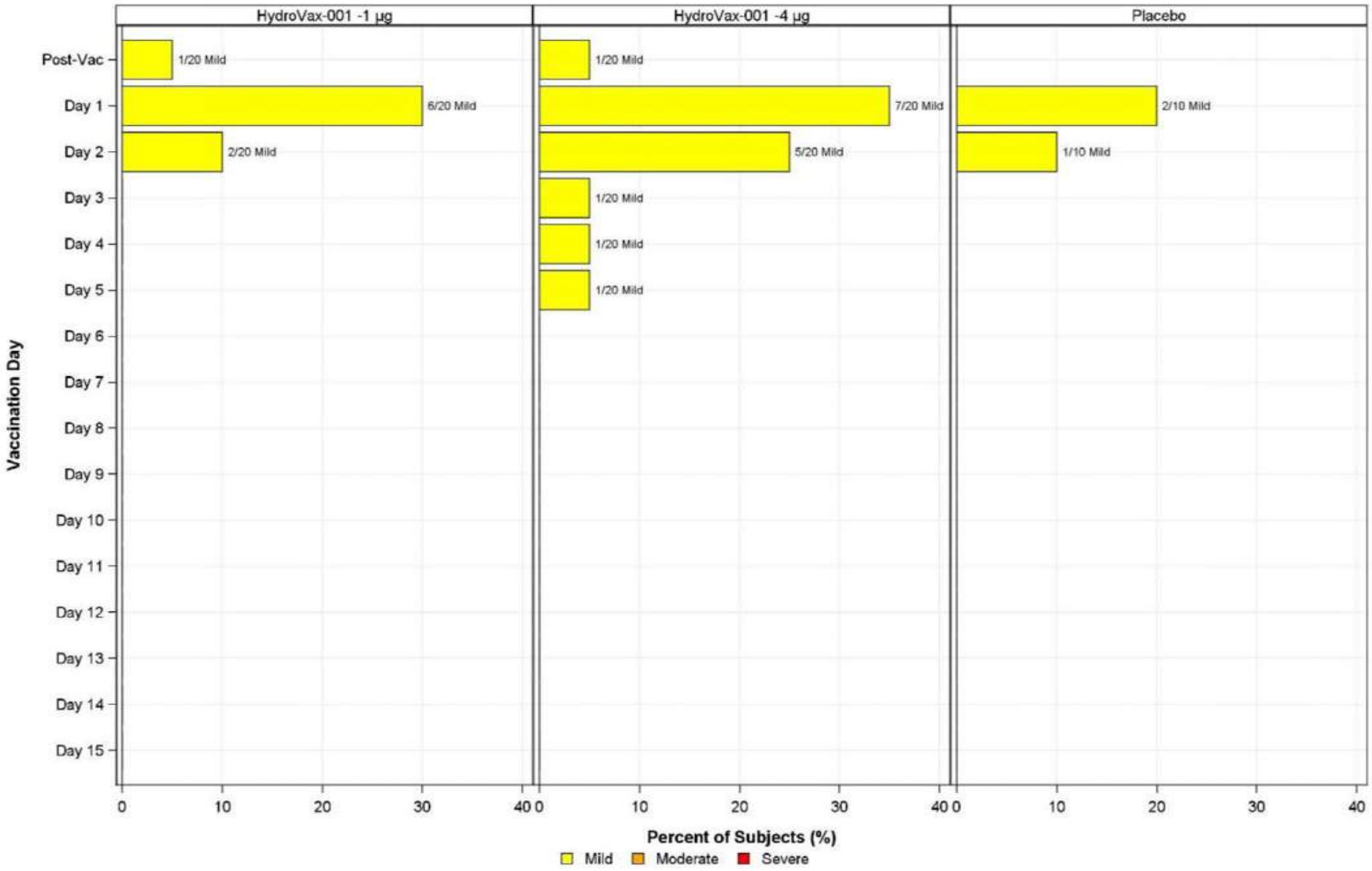
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 3: Maximum Severity of Solicited Systemic Symptoms per Subject by Day Post Treatment - Post-Dose 2



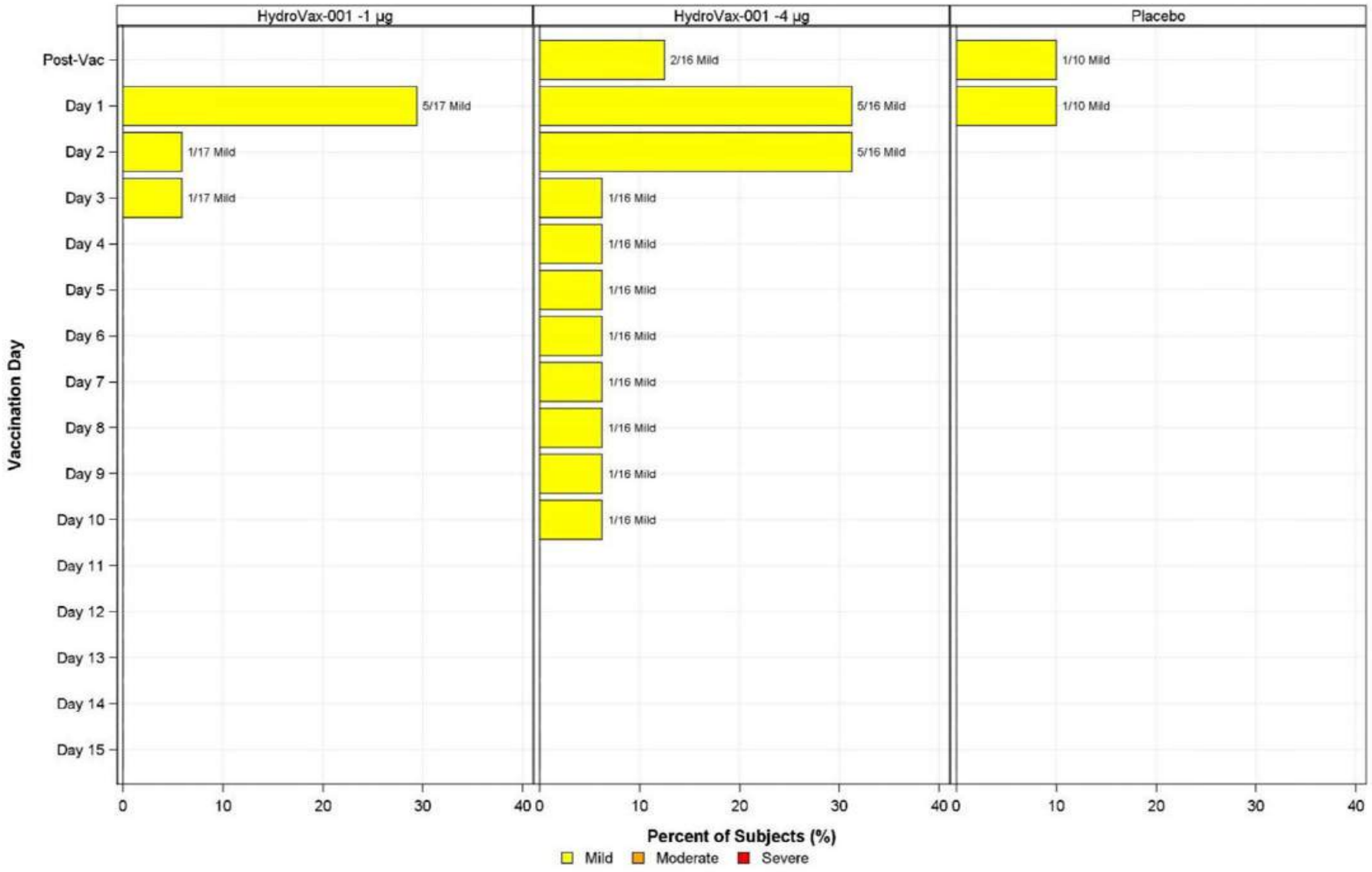
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 4: Maximum Severity of Solicited Local Symptoms per Subject by Day Post Treatment - Post-Dose 1



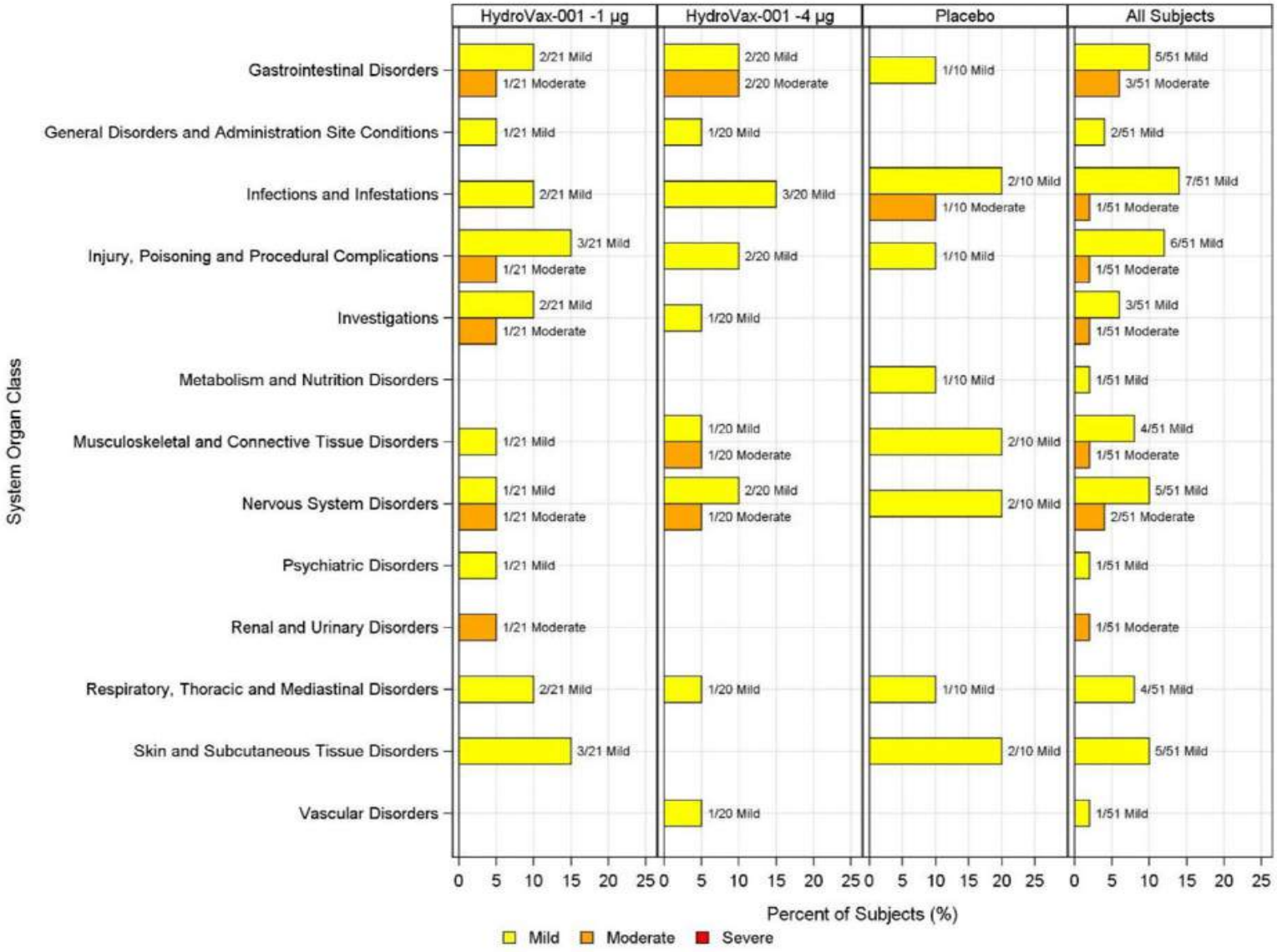
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 5: Maximum Severity of Solicited Local Symptoms per Subject by Day Post Treatment - Post-Dose 2



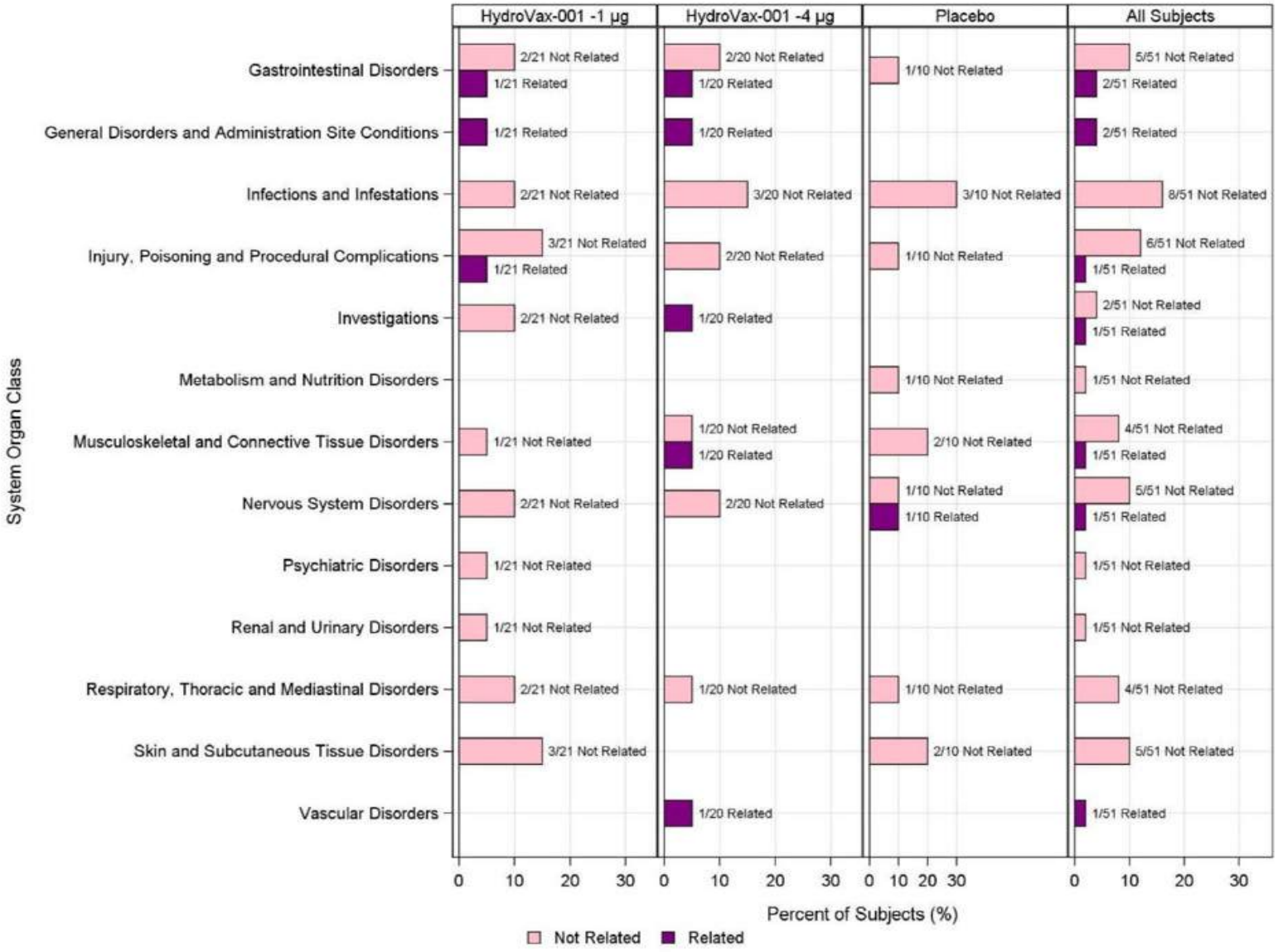
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 6: Incidence of Adverse Events by MedDRA® System Organ Class and Severity



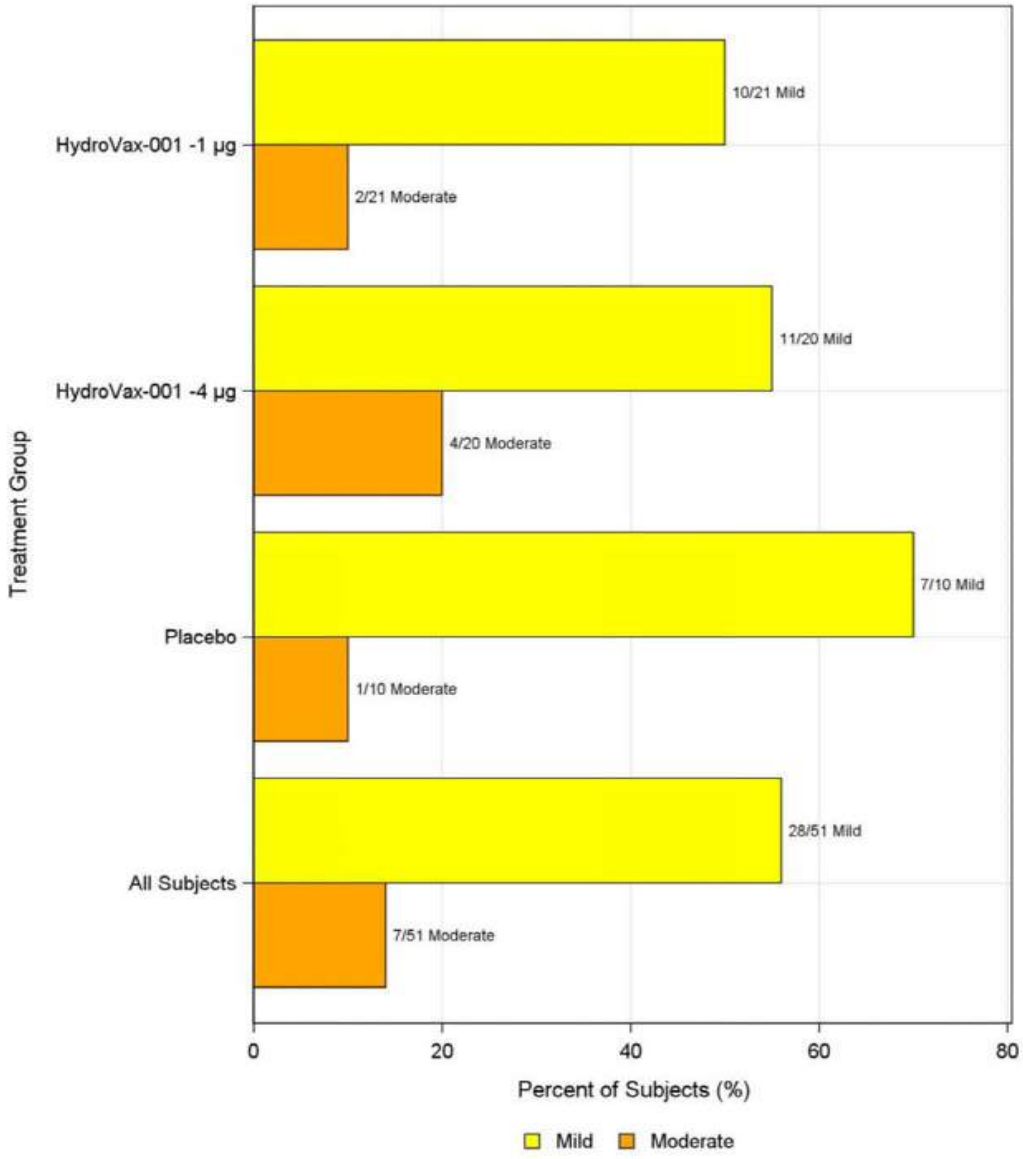
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 7: Incidence of Adverse Events by MedDRA® System Organ Class and Relationship to Treatment



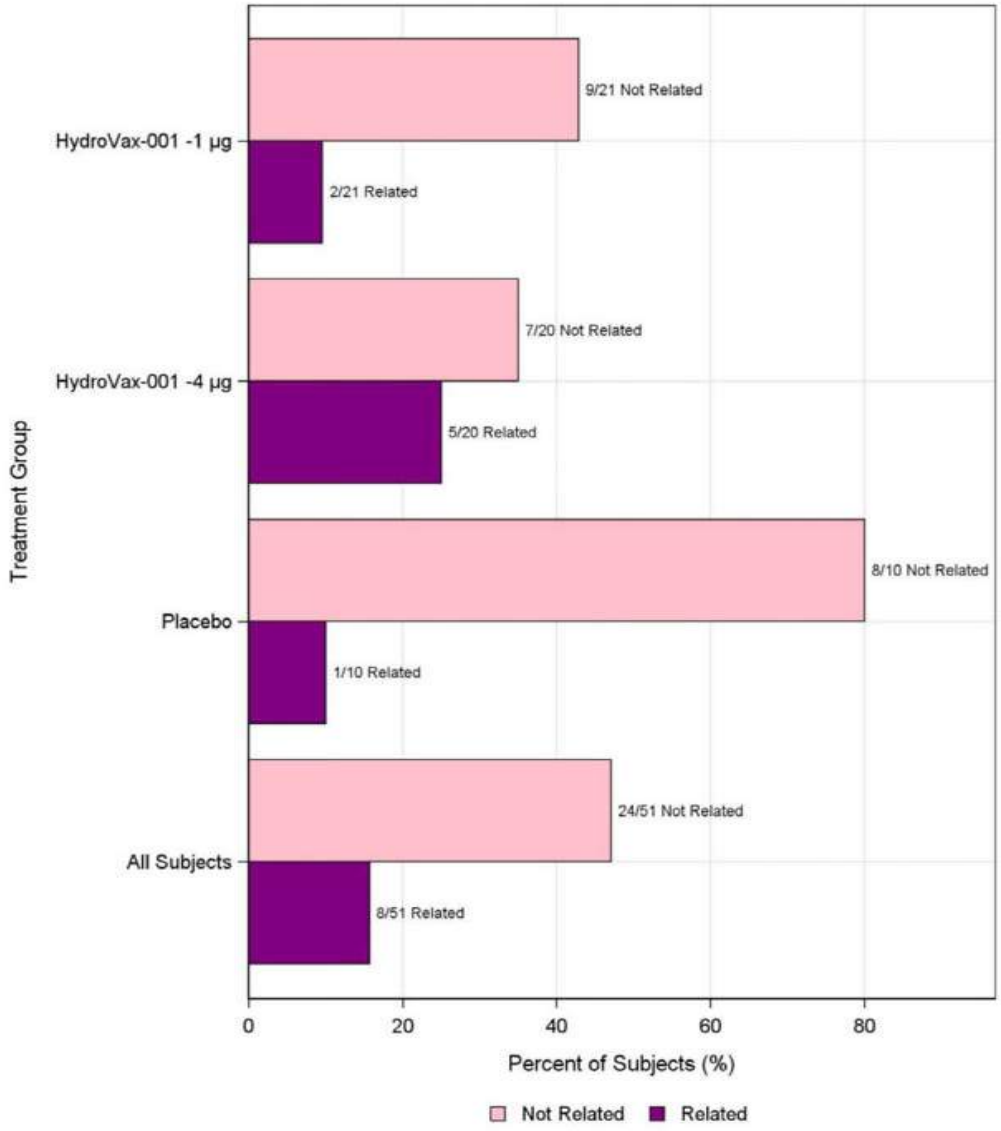
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 8: Incidence of Adverse Events by Severity



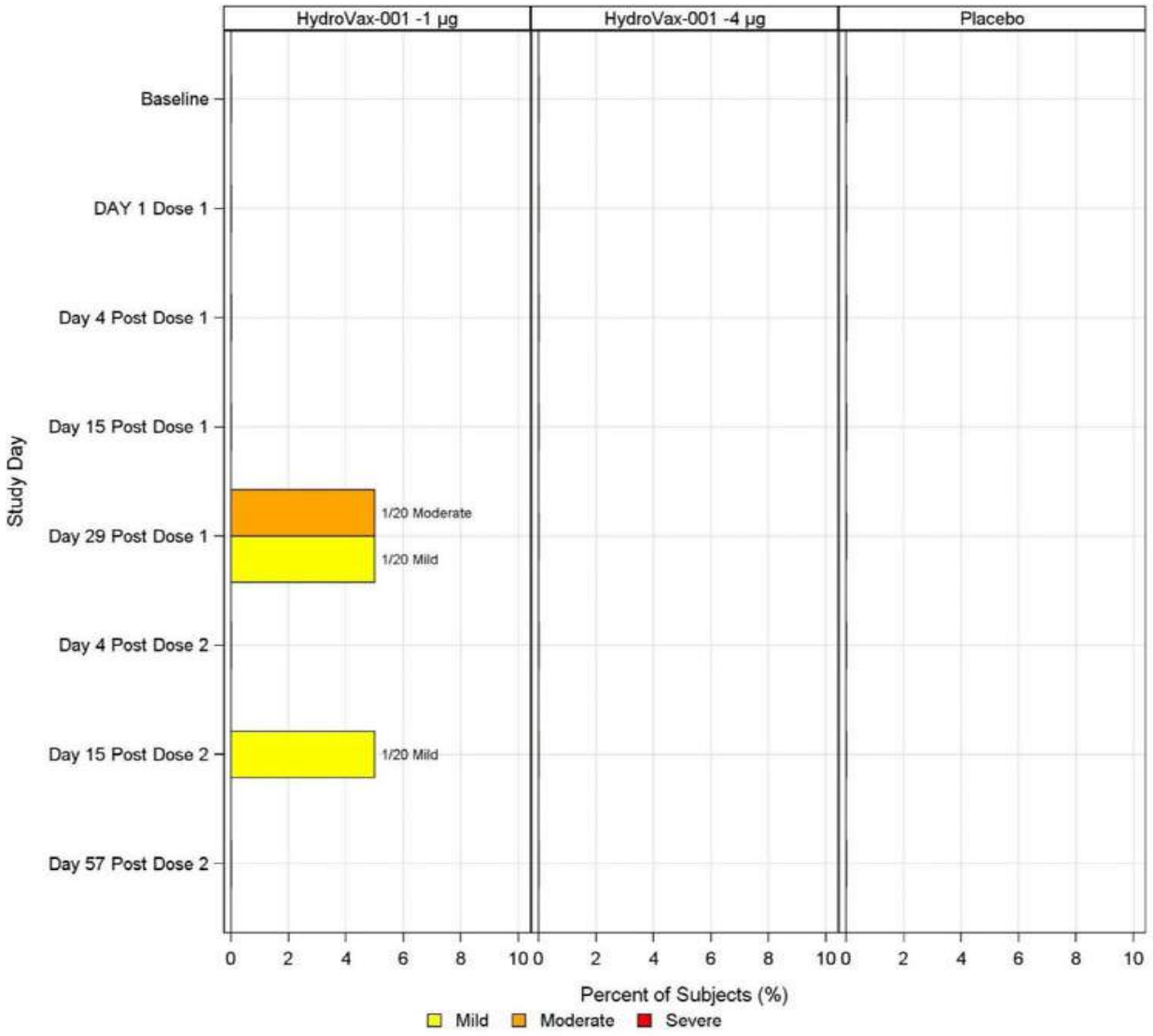
Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 9: Incidence of Adverse Events by Relationship to Treatment



Implementation Note: Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 10: Vital Signs by Assessment, Maximum Severity, Study Day, and Treatment Group



Implementation Note: Assessments will either be displayed in individual panels of a single figure or in separate figures. Treatment group labels in the shell are generic. The actual labels will be used in the production version.

Figure 11: Reverse Cumulative Distribution of $PRNT_{50}$ by Study Day, HydroVax-002 YFV 1 mcg, Full Analysis Population

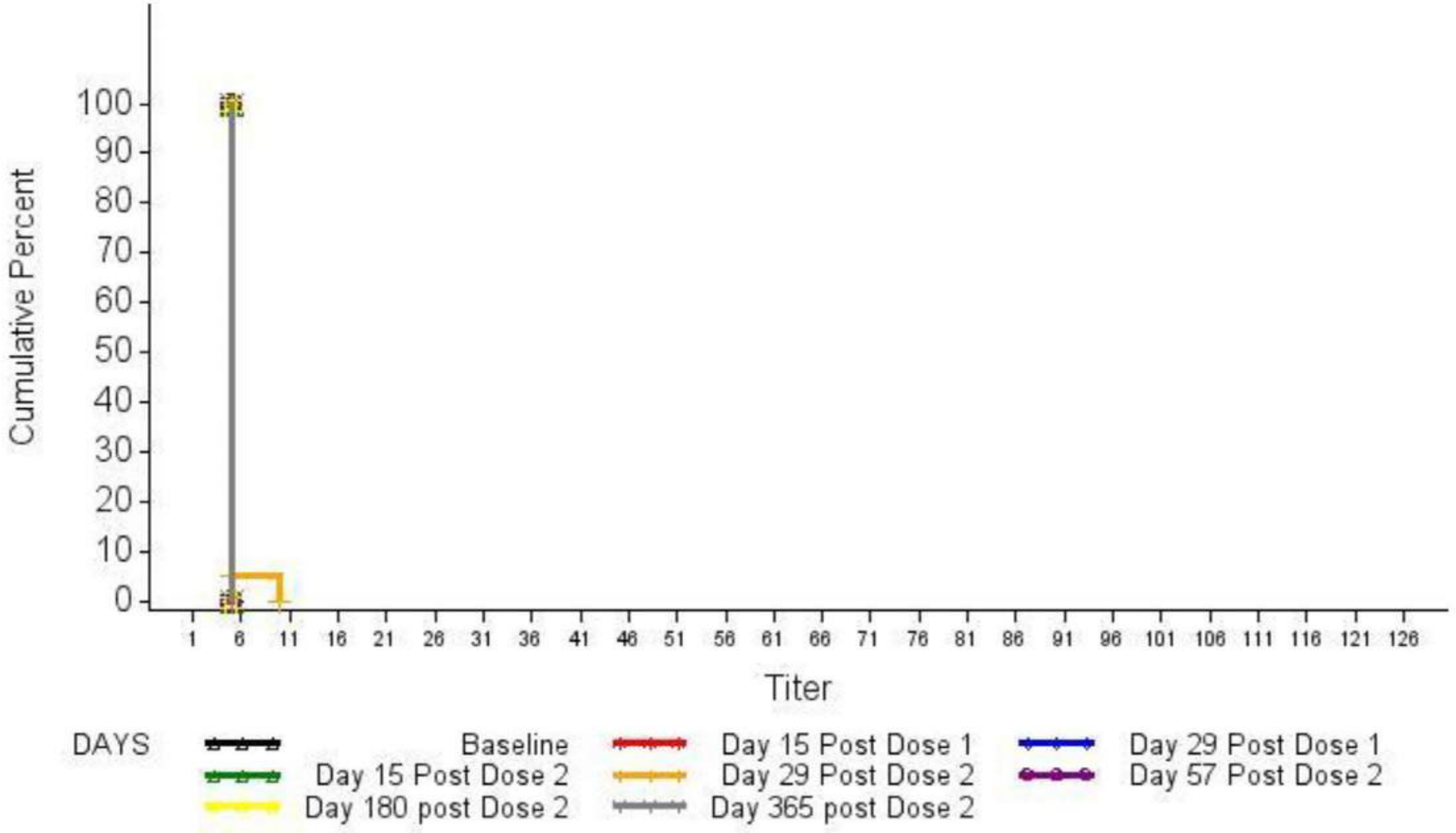


Figure 12: Reverse Cumulative Distribution of $PRNT_{50}$ by Study Day, HydroVax-002 YFV 5 mcg, Full Analysis Population

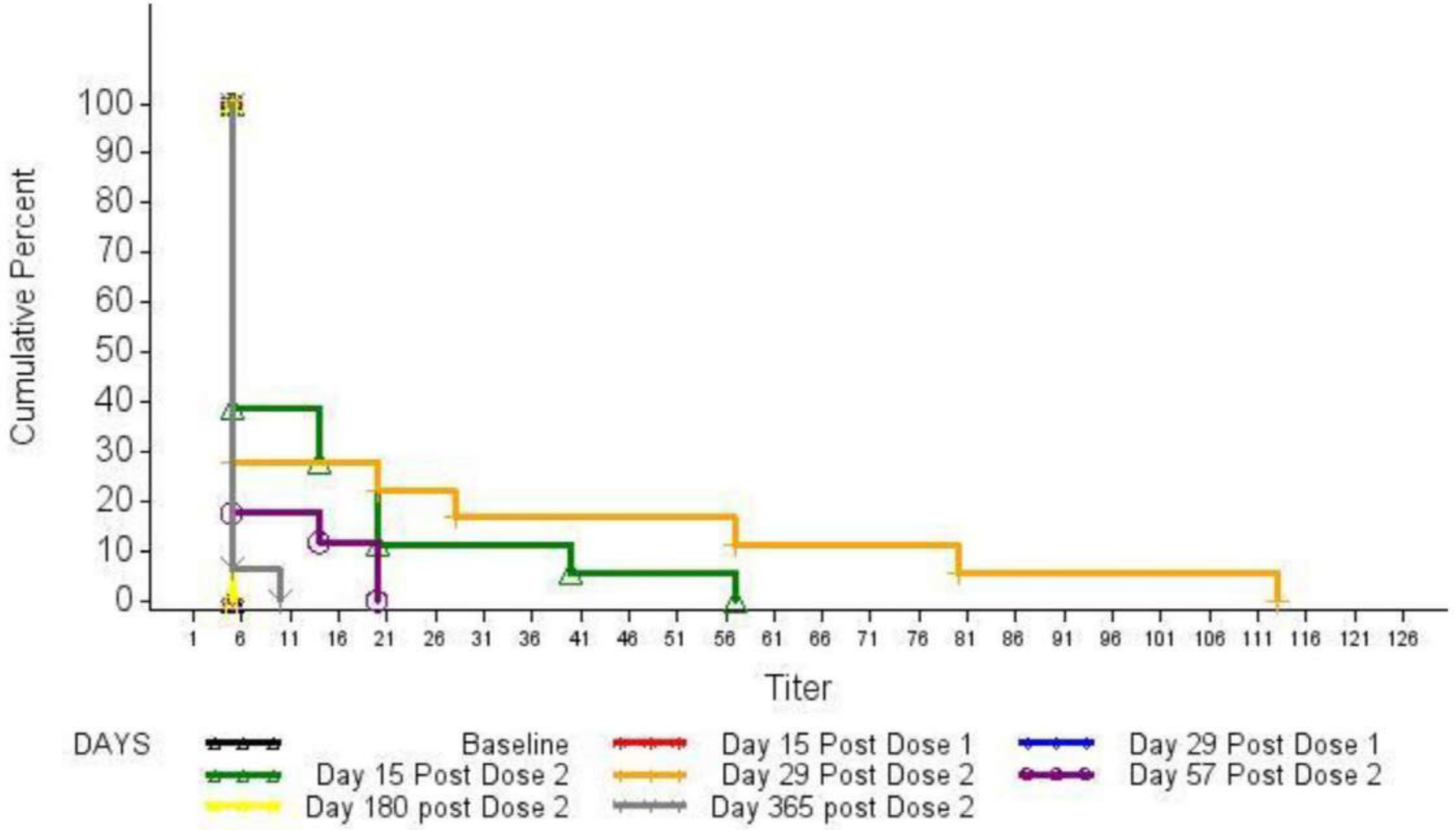


Figure 13: Reverse Cumulative Distribution of $PRNT_{50}$ by Study Day, HydroVax-002 YFV 1 mcg, Per Protocol Population

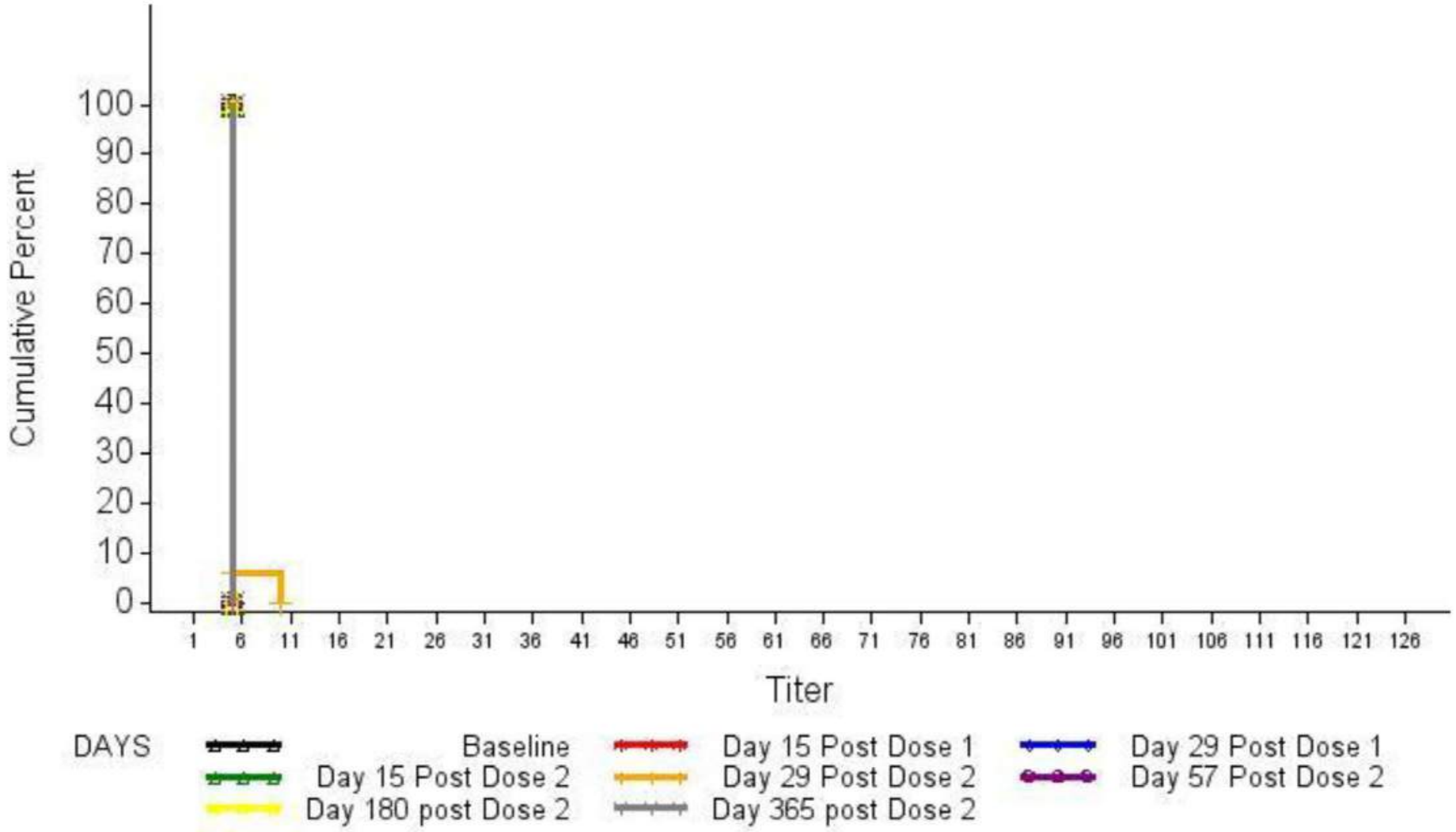


Figure 14: Reverse Cumulative Distribution of $PRNT_{50}$ by Study Day, HydroVax-002 YFV 5 mcg, Per Protocol Population

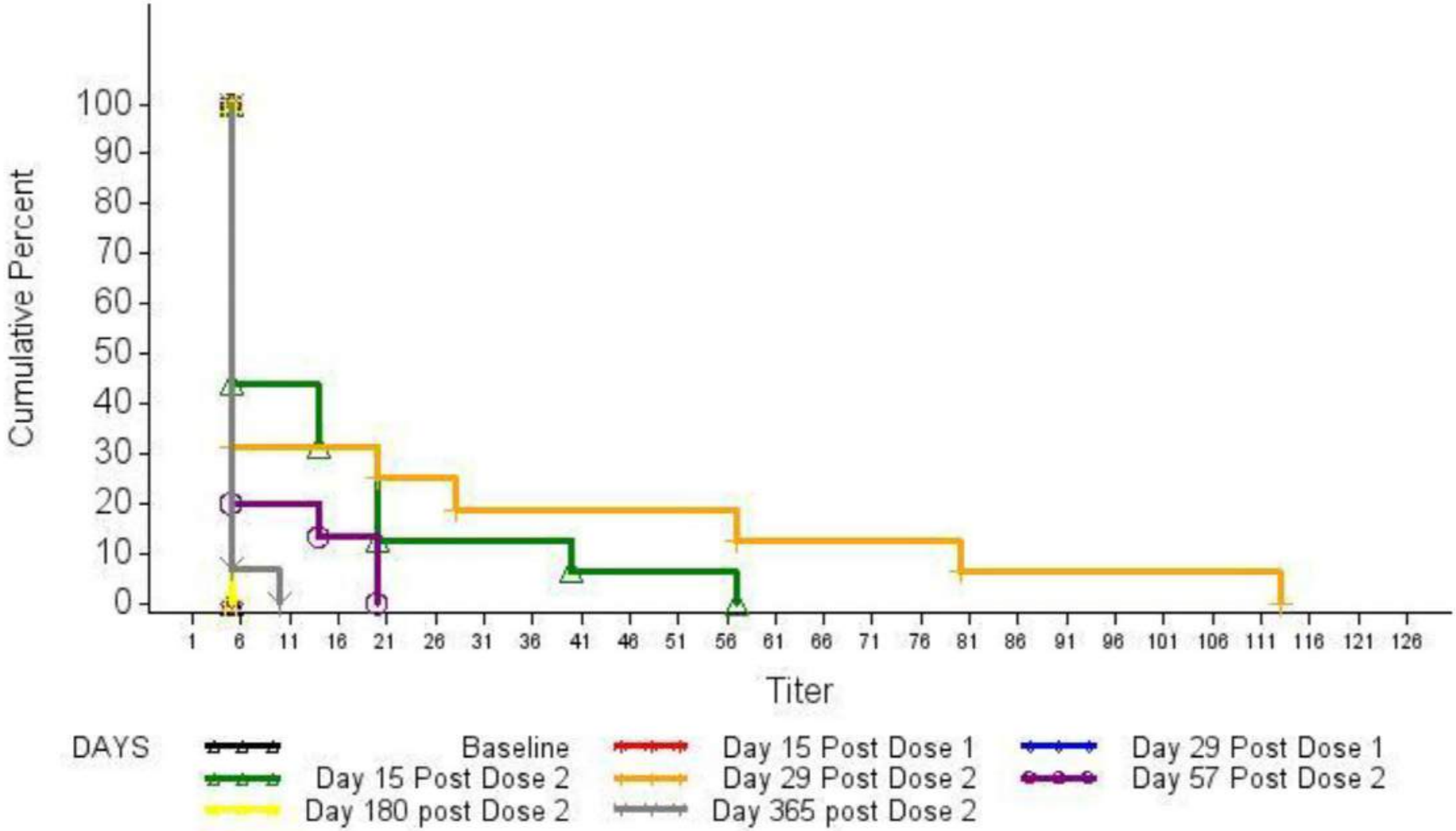


Figure 15: Reverse Cumulative Distribution of Log Neutralizing Index (LNI) by Study Day, HydroVax-002 YFV 1 mcg, Full Analysis Population

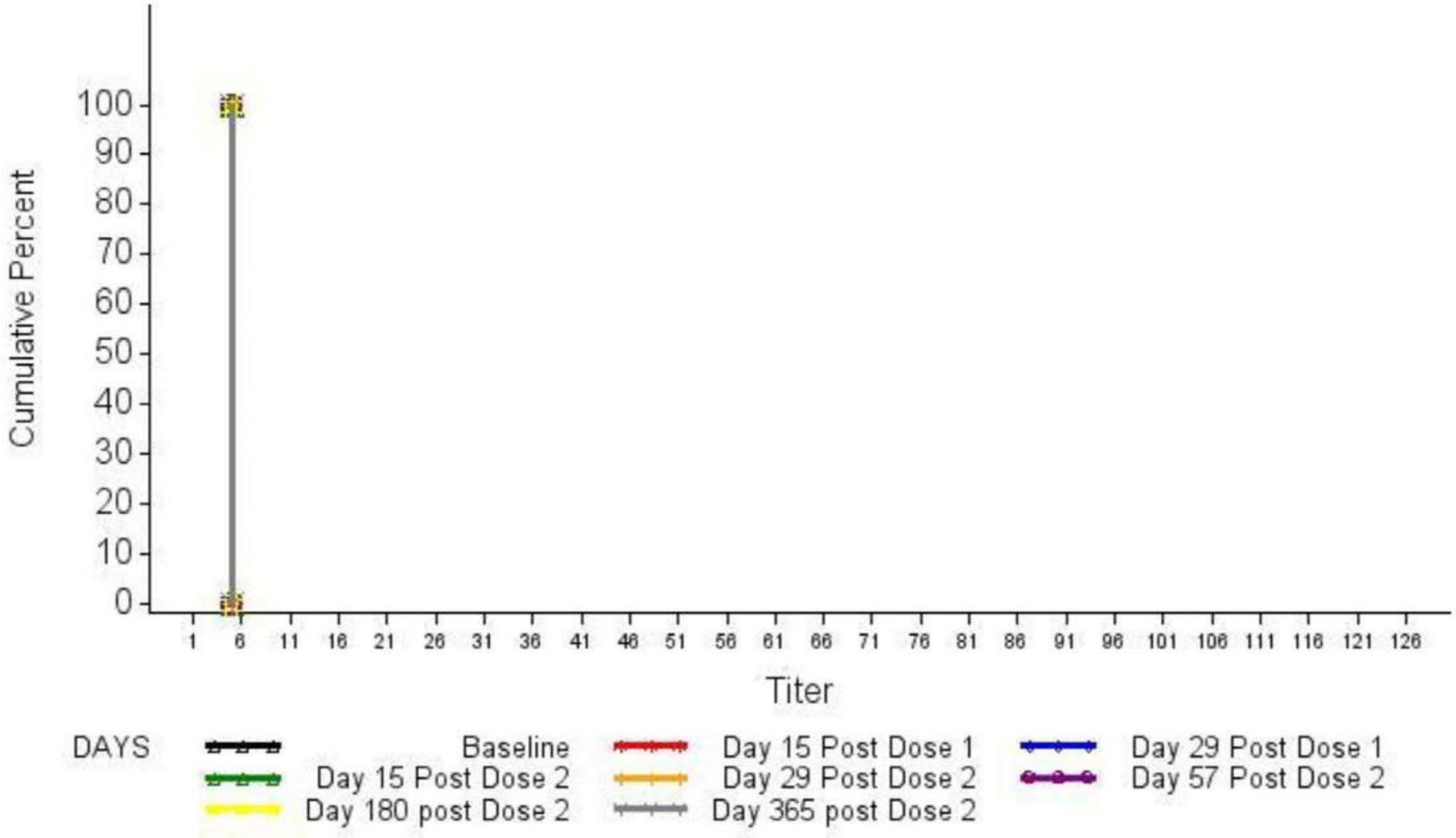


Figure 16: Reverse Cumulative Distribution of Log Neutralizing Index (LNI) by Study Day, HydroVax-002 YFV 5 mcg, Full Analysis Population

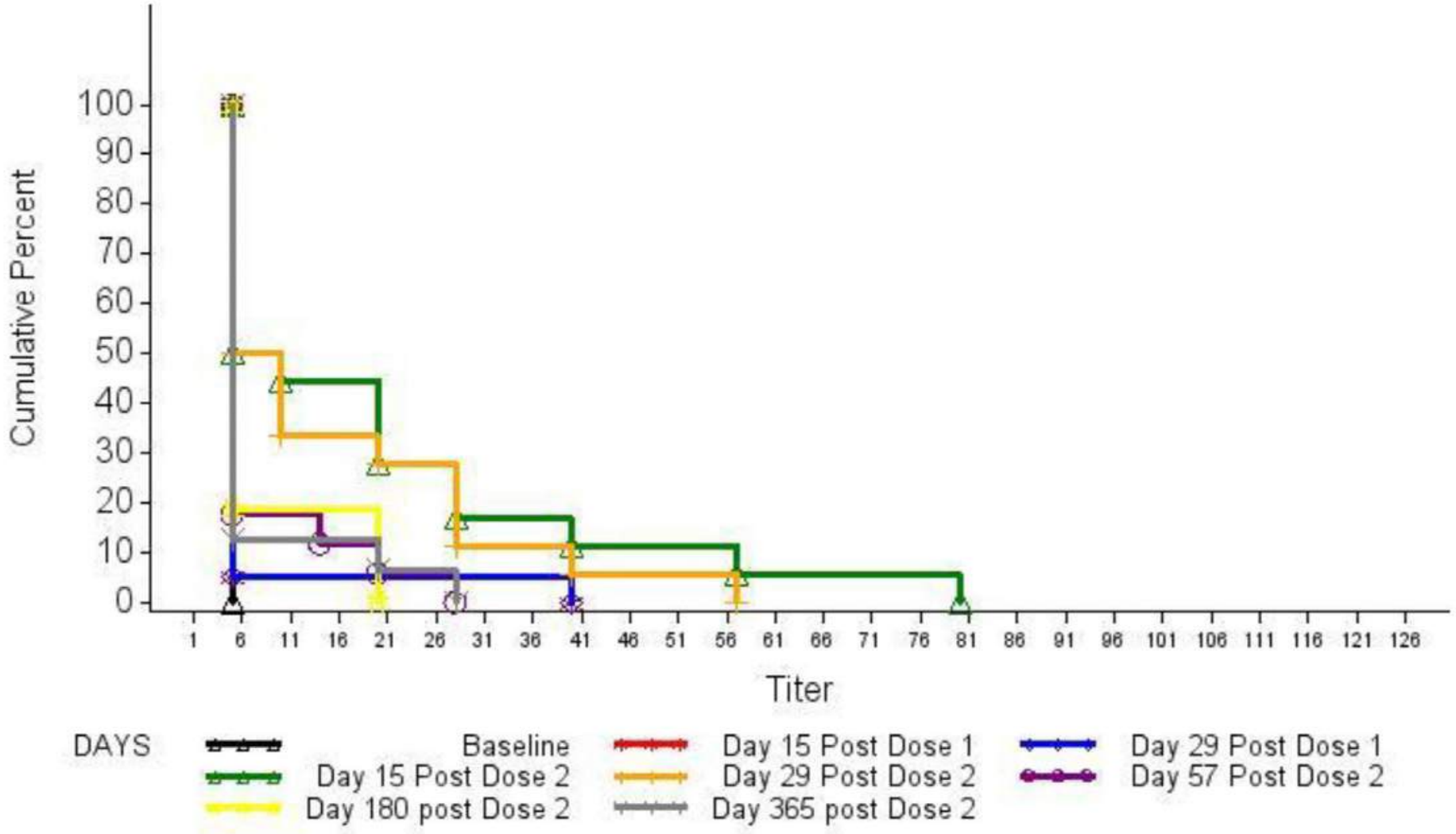


Figure 17: Reverse Cumulative Distribution of Log Neutralizing Index by Study Day, HydroVax-002 YFV 1 mcg, Per Protocol Population

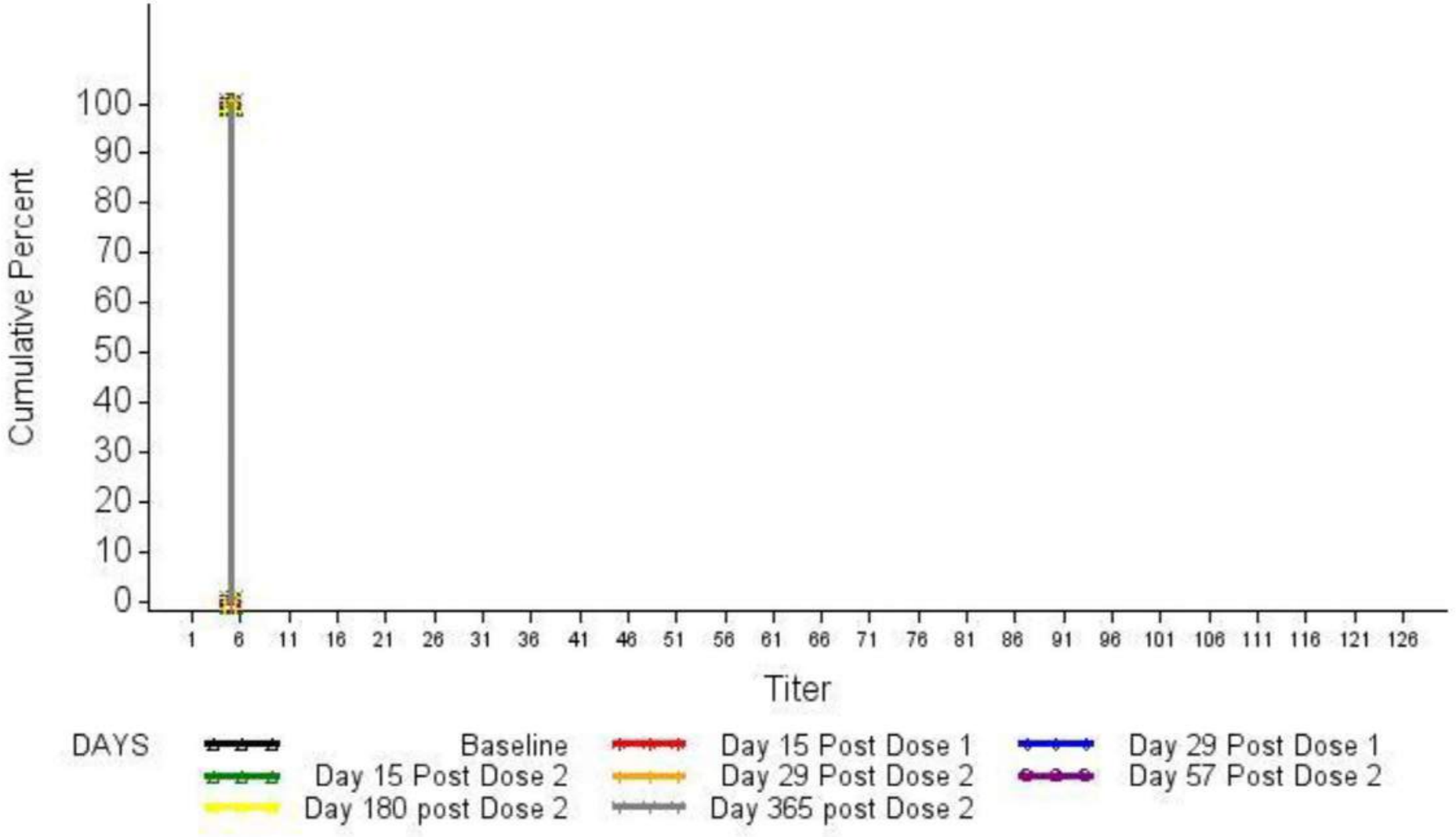


Figure 18: Reverse Cumulative Distribution of Log Neutralizing Index (LNI) by Study Day, HydroVax-002 YFV 5 mcg, Per Protocol Population