CLINICAL RESEARCH IN INFECTIOUS DISEASES

STATISTICAL ANALYSIS PLAN
for
DMID Protocol: 19-0003
Study Title:
First-in-Human Safety and Immunogenicity Evaluation of an Intramuscular *Campylobacter jejuni* Conjugate Vaccine (CJCV2) with and without Army Liposome Formulation containing QS-21 (ALFQ)

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RESTRICTED

STUDY TITLE

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This study was performed in compliance with Good Clinical Practice.

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LIST OF ABBREVIATIONS

3D-PHAD®	Monophosphoryl 3-deacyl lipid A (synthetic)
AE	Adverse Event
ALFQ	Army Liposome Formulation containing QS-21
ALS	Antibodies in Lymphocyte Supernatant
ALT	Alanine Aminotransferase
ANC	Absolute Neutrophil Count
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
BP	Blood Pressure
bpm	Beats Per Minute
cGMP	Current Good Manufacturing Practices
CI	Confidence Interval
CJCV2	*Campylobacter jejuni* Conjugate Vaccine 2
CPS	Capsular Polysaccharide
CRF	Case Report Form
CRM_{197}	Cross-Reactive Material 197
CSR	Clinical Study Report
DMID	Division of Microbiology and Infectious Diseases
eCRF	Electronic Case Report Form
ELISA	Enzyme-linked Immunosorbent Assay
F	Fahrenheit
FDA	Food and Drug Administration
FR	Fold-Rise
GBS	Guillain-Barré Syndrome
GMT	Geometric Mean Titer
GMFR	Geometric Mean Fold-Rise
HBsAg	Hepatitis B Surface Antigen

List of Abbreviations *(continued)*

HCV	Hepatitis C Antibody
Hgb	Hemoglobin
HIV	Human Immunodeficiency Virus
HLA-B27	Human Leukocyte Antigen B27
HR	Heart Rate
ICD-10	International Classification of Diseases - 10th Revision
ICF	Informed Consent Form
ICH	International Council for Conference on Harmonisation
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IM	Intramuscular
LOD	Limit of Detection
LLOQ	Lower Limit of Quantification
MAAE	Medically Attended Adverse Event
MedDRA	Medical Dictionary for Regulatory Activities
MeOPN	*O*-methyl phosphoramidate
MOP	Manual of Procedures
N	Number (typically refers to participants)
n	Number
NOCMC	New-Onset Chronic Medical Condition
OTC	Over the Counter
PBMC	Peripheral Blood Mononuclear Cell
PI	Principal Investigator
PIMMC	Potentially Immune-Mediated Medical Condition
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event

List of Abbreviations *(continued)*

SAP	Statistical Analysis Plan
SDCC	Statistical and Data Coordinating Center
SMC	Safety Monitoring Committee
SOC	System Organ Class
SRC	Safety Review Committee
SUSAR	Suspected Unexpected Serious Adverse Reaction
T. bili	Total Bilirubin
ULN	Upper Limit of Normal
USP	United States Pharmacopeia
WBC	White Blood Cell
WHO	World Health Organization

1. PREFACE

The Statistical Analysis Plan (SAP) for "First-in-Human Safety and Immunogenicity Evaluation of an Intramuscular *Campylobacter jejuni* Conjugate Vaccine (CJCV2) with and without Army Liposome Formulation containing QS-21 (ALFQ)" (DMID Protocol 19-0003) describes and expands upon the statistical information presented in the 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 final analyses. Regarding the final analyses and Clinical Study Report (CSR), this SAP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, as indicated in Topic E3 (Structure and Content of Clinical Study Reports), and more generally is consistent with Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials). The structure and content of the SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA) and ICH, while all work planned and reported for this SAP will follow internationally accepted guidelines published by the American Statistical Association and the Royal Statistical Society for statistical practice.

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

2. INTRODUCTION

Campylobacter species are among the most common causes of diarrheal disease worldwide with *C. jejuni* being the primary species associated with human disease [1]. Campylobacteriosis ranges from hyperendemic levels (prevalence up to 84.9% in children <1 year of age) in developing regions [2], to sporadic disease in young adults and infants, in developed countries [3], or traveler's diarrhea in persons from industrialized countries, including deployed troops, visiting hyperendemic regions [4-7]. *Campylobacter* is one of the most severe forms of travelers' diarrhea with a longer duration, increased numbers of unformed stools, and more frequent association with abdominal pain, nausea, vomiting and fever in comparison to the other common causes [3, 5, 7-9]. In addition to the acute effects, *Campylobacter* infection is associated with a number of important sequelae, including Guillain-Barré syndrome (GBS), reactive arthritis, irritable bowel syndrome and, to a lesser extent, inflammatory bowel disease [10-15]. *Campylobacter* is the most common bacterial cause of foodborne illnesses in the United States; in 2016 the Centers for Disease Control and Prevention Foodborne Diseases Active Surveillance Network reported 24,029 foodborne infections, 5,512 hospitalizations, and 98 deaths [3]. Globally, *Campylobacter* is 1 of the 4 key global causes of diarrheal diseases [9]. The high incidence of *Campylobacter* diarrhea, as well as its duration and possible complications, makes it highly important from a socio-economic perspective. In developing countries, *Campylobacter* infections in children under the age of 2 years are especially frequent, sometimes resulting in death. Until recently, campylobacteriosis has been viewed as a self-limited illness ameliorated by antibiotic treatment. However, the resistance of *Campylobacter* to many antibiotics, particularly fluoroquinolones, is rapidly rising as a single point mutation is sufficient for the development of resistance [16-18]. Thus, alternative measures to control the infection, including vaccination, are required.

2.1. Purpose of the Analyses

These analyses, which will be included in the clinical study report, will assess the safety and immunogenicity of CJCV2 [a vaccine comprised of a capsular polysaccharide (CPS) of *C. jejuni* conjugated to Cross-Reactive Material 197 (CRM_{197})] and whether the adjuvant ALFQ will enhance the immune response without significantly altering safety of CJCV2.

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives

Primary

- Evaluate the safety of the three different doses of IM injection of CJCV2 with and without ALFQ

Secondary

- Evaluate *C. jejuni* capsule-specific serum IgG responses following vaccination

Exploratory

- Evaluate CRM_{197}-specific serum IgG responses
- Evaluate *C. jejuni* capsule-specific IgG in antibodies in lymphocyte supernatant (ALS)
- Evaluate *C. jejuni* capsule-and CRM_{197}-specific serum IgM responses

3.2. Endpoints

Primary

- Occurrence of solicited local and systemic AEs through 7 days after each study vaccination
- Occurrence of vaccine-related unsolicited AEs through 28 days post last vaccination
- Occurrence of serious adverse events (SAEs) through approximately 12 months post last vaccination
- Occurrence of medically attended adverse events (MAAEs), new-onset chronic medical conditions (NOCMCs), and potentially immune-mediated medical conditions (PIMMCs) from the time of the first study vaccination through approximately 12 months (or throughout the period of their study participation) following the last vaccination

Secondary

- Development of a ≥ 4-fold rise from baseline in *C. jejuni* capsule-specific IgG serum antibodies at Days 8, 29, 36, 57, 64, 85 and 113.
- Peak fold rise from baseline in *C. jejuni* capsule-specific IgG serum antibody titer across Days 8, 29, 36, 57, 64, 85 and 113
- Maximum *C. jejuni* capsule-specific IgG serum antibody titer across Days 8, 29, 36, 57, 64, 85 and 113

Exploratory

- Development of a ≥ 4-fold rise from baseline in CRM_{197}-specific IgG serum antibodies at Days 8, 29, 36, 57, 64, 85 and 113
- Peak fold rise from baseline in CRM_{197}-specific IgG serum antibody titer across Days 8, 29, 36, 57, 64, 85 and 113
- Maximum CRM_{197}-specific IgG serum antibody titer across Days 8, 29, 36, 57, 64, 85 and 113
- Development of a ≥ 4-fold rise from baseline in *C. jejuni* capsule-specific IgG antibodies in lymphocyte supernatant at Days 8, 36 and 64

- Peak fold rise from baseline in *C. jejuni* capsule-specific IgG antibodies in lymphocyte supernatant across Days 8, 36 and 64
- Maximum *C. jejuni* capsule-specific IgG antibodies in lymphocyte supernatant titer across Days 8, 36 and 64
- Development of a ≥ 4-fold rise from baseline in *C. jejuni* capsule-specific serum IgM at Days 8, 29, 36, 57, 64, 85 and 113
- Development of a ≥ 4-fold rise from baseline in CRM_{197}-specific serum IgM at Days 8, 29, 36, 57, 64, 85 and113
- Peak fold rise from baseline in *C. jejuni* capsule-specific serum IgM titer across Days 8, 29, 36, 57, 64, 85 and 113
- Peak fold rise from baseline in CRM_{197}-specific serum IgM titer across Days 8, 29, 36, 57, 64, 85 and 113
- Maximum *C. jejuni* capsule-specific serum IgM titer across Days 8, 29, 36, 57, 64, 85 and 113
- Maximum CRM_{197}-specific serum IgM titer across Days 8, 29, 36, 57, 64, 85 and 113

3.3. Study Definitions and Derived Variables

Unless otherwise specified, the baseline value will be defined as the last value obtained prior to the first vaccination. Vital signs assessed on Day 1 prior to study vaccination will be considered as baseline. Any medical condition that is present at the time that the participant is screened will be considered as baseline and will only be reported as an AE if symptoms related to the condition occur with greater frequency and/or severity after vaccination during the AE reporting period.

Change from baseline is defined as the additive change from baseline, i.e., $CHG_{ij} = y_{ij} - y_{i0}$ where y_{ij} is the measurement for participant *i* at time point *j* and y_{i0} is the measurement for participant *i* at baseline (prior to vaccination 1).

Fold-rise (FR) from baseline is defined as the multiplicative change from baseline, i.e., $FR_{ij} = \frac{y_{ij}}{y_{i0}}$ where y_{ij} is the response for participant *i* at time point *j* and y_{i0} is the response for participant *i* at baseline (pre-vaccination 1). Individual FR values will be reported to 1 decimal place.

The peak titer and peak fold-rise are defined as the maximum value for a participant at any time after the first vaccination.

A responder is defined as having ≥ 4-fold increase relative to baseline, i.e., $FR_{ij} \geq 4$ for participant *i* at post-baseline time point *j*. For serum assays, participants are classified as responders or not at Days 8, 29, 36, 57, 64, 85, and 113; for the ALS assay, participants are classified as responders or not at Days 8, 36, and 64.

4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

This is a randomized, double-blind, dose-escalating, outpatient, first-in-human study to test the safety and immunogenicity of the CJCV2 vaccine with and without adjuvant ALFQ. A total of approximately 60 generally healthy adult participants (males and non-pregnant, non-lactating females) aged 18-50 years inclusive will be enrolled in 3 cohorts with 20 participants per cohort (Table 1). Each participant will receive three intramuscular (IM) vaccinations spaced 28 days apart. All participants within a cohort will receive the same fixed dose of CJCV2 (1 µg, 3 µg, or 10 µg) and will be randomized to receive the vaccinations with or without the adjuvant ALFQ (200 µg 3D-PHAD® and 100 µg QS-21 in Sorensen's Phosphate Buffered Saline) with a 1:1 allocation ratio. The first cohort will receive the lowest dose of CJCV2 (1 µg) with or without ALFQ, the second cohort will receive the next highest dose of CJCV2 (3 µg), and the third cohort will receive the highest dose of CJCV2 (10 µg).

As this is a first-in human study, there will be six sentinel participants in each of the 3 cohorts. No more than two sentinels will be dosed per day with a minimum of two hours between dosing. The Safety Review Committee (SRC) composed of the PI, DMID Medical Monitor, and DMID Medical Officer will review safety data from the six sentinel participants through 7 days post first vaccination to determine if the rest of the cohort may be vaccinated. If no safety signal is detected, the remaining 14 participants in the cohort will be vaccinated. The SRC will also review safety data through Study Day 64 from all participants in Cohort 1 prior to starting enrollment of Cohort 2 at the next highest dose. Similar reviews conducted by the SRC will occur after the Cohort 2 sentinels receive their first vaccination prior to enrolling the remainder of Cohort 2, after all Cohort 2 participants have received all vaccinations prior to enrolling the Cohort 3 sentinels, and after the Cohort 3 sentinels receive their first vaccination prior to enrolling the remainder of Cohort 3.

Additional safety oversight will be conducted by an independent Safety Monitoring Committee (SMC) composed of at least 3 voting members with appropriate Phase 1 study expertise to evaluate the safety data from this trial. The SMC will meet prior to study initiation, if a halting rule is met, or if any other safety concerns are identified during the trial (including but not limited to any concerns noted by the SRC during the sentinel or dose escalation safety reviews).

A schedule of study procedures is presented in Table 2.

The vaccinations will be performed by unblinded study staff, but the participant, study staff performing any post-vaccination assessments, and laboratory personnel will be blinded.

This study will utilize direct data entry for data collection, i.e., study staff will enter clinical data directly into electronic Case Report Forms (eCRFs) in real time. Additional details are in the study Manual of Procedures (MOP).

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

Three doses (1 µg, 3 µg and 10 µg) of CJCV2 will be evaluated with and without ALFQ; see Section 4.4.2 for discussion of the selection of these doses.

As this is a first-in-human study, interim safety reviews occurring after 6 sentinel participants in each cohort and before dose escalation in the next cohort are conducted to minimize risks to participants.

This trial does not use a placebo control as the goal is to study safety and reactogenicity of the study vaccine with and without ALFQ.

4.3. Selection of Study Population

Cohort 1 was enrolled under protocol v4.0 (25MAY2022), and Cohorts 2 and 3 were enrolled under protocol v6.0 (08MAY2023); the full list of inclusion and exclusion criteria can be found in the specified versions of the protocol. The inclusion and exclusion criteria were updated between the enrollment of Cohort 1 and Cohort 2 to be less restrictive. The major differences are listed below:

- The inclusion criteria in v4.0 required a Body Mass Index (BMI) < 36; this was changed to BMI < 40 in v6.0.
- The exclusion criteria in v4.0 excluded participants with "documented family history of auto-immune conditions"; this was changed to "documented history of auto-immune conditions in a first-degree relative" in v6.0.
- The exclusion criteria in v4.0 excluded participants with "travel to countries with high Campylobacter rates (to include Asia, Africa, and Central and South America) within two years prior to dosing." This exclusion criterion was removed in v6.0.

4.4. Treatments

4.4.1. Treatments Administered

The investigational products are the vaccine CJCV2 and the adjuvant ALFQ. CJCV2 is a purified HS23/36 CPS of *Campylobacter jejuni* conjugated to CRM_{197}. ALFQ consists of two active components, a synthetic monophosphoryl lipid A, 3D-PHAD®, and QS-21, a purified saponin extracted from the bark of the *Quillaja saponaria* tree.

4.4.2. Identity of Investigational Product(s)

CJCV2

The vaccine to be evaluated in the current project is a *C. jejuni* capsule conjugate vaccine named CJCV2 produced from an engineered mutant of 81-176 that is lacking an enzyme responsible for the production of a lipooligosaccharide that could potentially trigger GBS. In contrast to the strain used for CJCV1 (which was made from strain 3208), a natural variant of 3208 (named 3208.1) was selected that presents the two *O*-methyl phosphoramidate (MeOPN) transferases in the "on" status to ensure that there is an optimum amount of MeOPN on the capsule. The CPS is conjugated to CRM_{197}, a non-toxic mutant protein of diphtheria toxin at a CPS: CRM_{197} ratio of 2:1. The CJCV2 vaccine product was manufactured at Inventprise LLC (Redmond, Washington) with final fill and finish completed by The University of Iowa Pharmaceuticals (Iowa City, Iowa), both performed under current Good Manufacturing Practices (cGMP) conditions.

ALFQ

ALFQ is composed of ALF55, QS-21, and Sorensen's Phosphate Buffer. ALF55 is a cGMP-manufactured Army Liposome Formulation containing the phospholipids dimyristoyl phosphatidyl choline and dimyristoyl phosphatidyl glycerol, 3D-PHAD® and 55% cholesterol. Cholesterol serves as a structural lipid and binds to QS-21. QS-21 is a purified saponin extracted from the bark of the *Quillaja saponaria* tree. ALFQ was manufactured at the Walter Reid Army Institute for Research Pilot Bioproduction Facility (Silver Spring, Maryland).

Formulations

The sterile lyophilized CJCV2 product is to be reconstituted in 1 mL of sterile water for injection. The resuspended CJCV2 product will be diluted with sterile 0.9% Sodium Chloride for Injection, United States Pharmacopeia (USP) to a bulk 2x CJCV2 working solution (Cohort 1: 2 µg/mL, Cohort 2: 6 µg/mL or Cohort 3: 20 µg/mL).

For participant-specific formulation, a total of 0.6 mL of the bulk 2x CJCV2 working solution will be transferred and mixed with a vial containing 0.6 mL of the adjuvant ALFQ or 0.6 mL of sterile 0.9% Sodium Chloride for Injection, USP to prepare 1.2 mL of a final 1x CJCV2 formulation (Cohort 1: 1 µg/mL, Cohort 2: 3 µg/mL or Cohort 3: 10 µg/mL). One milliliter will be drawn into a syringe to be injected intramuscularly to achieve the final quantity of deliverable active CJCV2 component as described above and the full dose of ALFQ (200 µg 3D-PHAD®, 100 µg QS-21) in participants receiving the adjuvant plus CJCV2. Further details of formulation and administration are included in the study MOP.

4.4.3. Method of Assigning Participants to Treatment Groups (Randomization)

Enrollment/randomization was performed through the enrollment module in the electronic data capture system maintained by the SDCC (Statistical and Data Coordinating Center).

Eligible participants were randomized and assigned in a 1:1 ratio to CJCV2:CJCV2+ALFQ. The randomization used a block randomization scheme with random block sizes and was stratified by cohort.

4.4.4. Selection of Doses in the Study

The doses of CJCV2 were selected because 1 µg is thought to be the lowest dose that will stimulate an immune response, 3 µg is likely to stimulate an effective immune response, and 10 µg is the highest dose that would be practical to use in a multivalent vaccine (the long-term plan for a vaccine against *Campylobacter*). The three-dose regimen and use of ALFQ was based on previous evaluation of a 1st generation *Campylobacter* vaccine named CJCV1 which demonstrated that 2 doses of vaccine using aluminum hydroxide as an adjuvant was safe, but immunogenicity was poor.

4.4.5. Selection and Timing of Dose for Each Participant

All participants will receive three doses of vaccine on Days 1, 29, and 57. A fixed dose of CJCV2 will be used for each cohort: 1 µg in Cohort 1, 3 µg in Cohort 2, and 10 µg in Cohort 3. Any participant assigned to receive ALFQ will receive the same fixed dose (200 µg 3D-PHAD and 100 µg QS-21). Participants in each cohort will be randomized using a 1:1 allocation ratio to receive either CJCV2 alone or CJCV2+ALFQ.

Sentinels will be dosed at least two hours apart with no more than two sentinels per day vaccinated.

Between the time of vaccination of the first six sentinels to 7 days after enrollment of the last sentinels, no new participants will be vaccinated, but screening may continue.

4.4.6. Blinding

This is a double-blind study. The CJCV2 vaccine with or without ALFQ will be prepared by the unblinded site pharmacist and will be administered by an unblinded vaccinator. Vaccination will be the only activity performed by the unblinded vaccinator. The unblinded vaccinator will transport the prepared vaccination in a dark colored UV split top bag to maintain the blind. Participants, investigators, study personnel performing any study-related assessments following study vaccine administration, and laboratory personnel performing antibody assays will be blinded to whether the participant received CJCV2 alone or CJCV2+ALFQ.

The randomization scheme will be generated by the SDCC and provided to unblinded study personnel performing study vaccination preparations.

The SMC may receive data in aggregate and presented by treatment group, but without the treatment group identified. The SMC may be unblinded to individual study treatment assignments of participants, as needed to adequately assess safety issues. The SRC may be unblinded to individual study treatment assignments of sentinel participants only, as needed to adequately assess safety before proceeding to enroll non-sentinel participants.

4.4.7. Prior and Concomitant Therapy

Administration of any medications or non-study vaccines will be documented in the appropriate eCRF. All concomitant medications taken in the 30 days prior to study enrollment through 28 days following last vaccination or early termination, whichever occurs first, will be recorded. All concomitant medications associated with SAEs, MAAEs, NOCMCs, and PIMMCs through the assessment period for these events will be recorded.

All prescription and over-the-counter medications as well as vitamins and supplements will be recorded.

Assessment of eligibility also will include a review of permitted and prohibited medications (per the exclusion criteria).

Use of new medications should prompt evaluation for the presence of an AE or new chronic medical condition.

Medications which may interfere with the evaluation of the investigational product should not be used unless absolutely necessary. Medications or treatments which are prohibited are listed in the exclusion criteria.

4.4.8. Treatment Compliance

All participants are to receive 3 doses of study product administered in the clinic. Participants will be directly observed at the time of dosing by a member of the clinical research team who is delegated to administer the study product, and administration of study product will be documented in the appropriate eCRF.

4.5. Immunogenicity and Safety Variables

4.5.1 Safety Variables

Safety was assessed through collection of solicited and unsolicited adverse events (AEs) and clinical safety laboratory evaluations.

Adverse Events

ICH E6 defines an AE as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product, regardless of its causal relationship to the study treatment. FDA defines an AE as any untoward medical occurrence associated with the use of a drug in humans, whether considered drug related.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of medicinal (investigational) product. The occurrence of an AE may come to the attention of study personnel during study visits and interviews of a study recipient presenting for medical care, or upon review by a study monitor.

All AEs will be captured on the appropriate eCRF. Information to be collected for AEs includes event description, date of onset, and assessment of severity, relationship to study product and alternate etiology (assessed only by those with the training and authority to make a diagnosis and listed on the Form FDA 1572 as an investigator/sub-investigator), date of resolution, seriousness, and outcome. The severity, relatedness, and seriousness of AEs will be determined using the following definitions and guidelines.

The severity of AEs will be assessed by the investigator using a protocol-defined grading system (Table 5, Table 6, and Table 7). For events not included in the protocol-defined grading system, the following guidelines will be used to quantify severity:

- Mild (Grade 1): Events that are usually transient and may require only minimal or no treatment or therapeutic intervention and generally do not interfere with the participant's usual activities of daily living.
- Moderate (Grade 2): Events that are usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research participant.
- Severe (Grade 3): Events interrupt usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention. Severe events are usually incapacitating.

The assessment of the AE's relationship to study product will be done by the study clinician licensed to make medical diagnoses and listed on the Form FDA 1572 as the site PI or sub-investigator. Whether the AE is related or not, is not a factor in determining what is or is not reported in this trial. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. In a clinical trial, the study product must always be suspect. The relationship to study product will be assessed for AEs using the terms related or not related:

- Related – There is a reasonable possibility that the study product caused the AE. Reasonable possibility means that there is evidence to suggest a causal relationship between the study product and the AE.
- Not Related – There is not a reasonable possibility that the administration of the study product caused the event.

An AE or suspected adverse reaction is considered a Serious Adverse Event (SAE) if, in the view of either the site PI or sponsor, it results in any of the following outcomes:

- death,
- a life-threatening adverse event, *Note: An AE is considered "life-threatening" if, in the view of either the site PI or sponsor, its occurrence places the patient or participant at immediate risk of death. It does not include an AE that, had it occurred in a more severe form, might have caused death.*
- inpatient hospitalization or prolongation of existing hospitalization,
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions,
- a congenital anomaly/birth defect.
- Important medical events that may not result in death, be life-threatening, or require hospitalizations may be considered serious when, based upon appropriate medical judgment they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes

listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

A SUSAR is an adverse event reaction that meets all three of the following criteria:

- Serious
- Unexpected
  - Unexpected event means an event unforeseen by the researcher or the participant, in terms of nature, severity, or frequency, and is not listed in the Investigator's Brochure, package insert, and/or summary of product characteristics.
- At least possibly related to the study product.

NOCMCs are defined as any new ICD-10 diagnosis that is applied to the participant during the duration of the study, after receipt of the study agent, that is expected to continue for at least 3 months and requires continued health care intervention.

MAAEs are any unsolicited AE for which a participant received medical attention, defined as hospitalization, an ER visit, or an otherwise unscheduled visit to or from medical personnel.

PIMMCs constitute a group of AEs that includes diseases which are clearly autoimmune in etiology and other inflammatory and/or neurologic disorders which may or may not have autoimmune etiologies. A list of qualifying conditions is in Appendix C of the protocol [v6.0, 08MAY2023].

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the severity of any pre-existing medical condition increases, it should be recorded as an AE.

Solicited adverse events are AEs that are common and known or expected to occur following the administration of the study product. Participants will be assessed for solicited AEs prior to and 30 minutes after each vaccine administration prior to the participant leaving the clinic. On the day of vaccination, participants will receive a thermometer and instructions to complete an e-memory aid to record symptoms for 7 days following each vaccination. The participant e-memory aid will be reviewed with the participant at study visits 48 hours and 7 days after each vaccination (Study Visits 02, 03, 06, 07, 10, and 11). Any symptoms still present after the solicited event collection period (Study Days 1-8 for first vaccination, Study Days 29-36 for second vaccination, and Study Days 57-64 for third vaccination) will continue to be followed until resolution or determined to be stable per investigator. Solicited events will be graded using the Toxicity Grading Scales in Table 5; for quantitative measurements of local injection site reactions, the grading scale classifications of "Small", "Medium", and "Large" will be presented as "Mild", "Moderate", and "Severe" respectively for consistency with other AEs.

- Solicited (local injection site) events listed for this protocol include qualitative measurements of pain, tenderness, ecchymosis, erythema, and induration/edema and quantitative measurements of ecchymosis, erythema, and induration/edema.
- Solicited (systemic) events listed in this protocol include fever (elevated oral temperature), feverishness, fatigue, malaise, myalgia, arthralgia, headache, nausea, and vomiting.

Unsolicited adverse events will be collected starting after the first vaccination through 28 Days after the last vaccination. SAEs, MAAEs, NOCMCs, and PIMMCs will be collected starting after the first vaccination through the final study visit.

Vital Signs

Per the MOP Appendix B, vital signs that meet the protocol-defined toxicity grading scale (Table 6) and represent a worsening condition from baseline are reported as an unsolicited AE with the exception of temperatures collected from the time of vaccination through 7 days post vaccination for each vaccination which will be reported as solicited AEs.

The last measurement prior to receiving the first vaccination for each parameter will be considered baseline.

Laboratory Safety Evaluations

Hematology laboratory measurements include WBC (white blood cells), Hgb (hemoglobin), platelet count, and absolute neutrophil count (ANC). Chemistry laboratory measurements include sodium, potassium, creatinine, Total bilirubin, and alanine aminotransferase (ALT). Chemistry and hematology assessments occurred at screening and 7 days post each vaccination (Study Visits 00, 03, 07, and 11); these assessments were also performed at unscheduled and early termination visits as indicated. The severity of laboratory AEs are graded using the protocol-defined scale in Table 7.

The last measurement prior to receiving the first vaccination for each parameter will be considered baseline.

4.5.2 Immunogenicity Variables

Serum from blood collected at Days 1, 8, 29, 36, 57, 64, 85, and 113 will be analyzed using an enzyme-linked immunosorbent assay (ELISA) to measure *C. jejuni* capsule-specific IgG serum antibody titers, CRM_{197}-specific IgG serum antibody titers, *C. jejuni* capsule-specific IgM serum antibody titers, and CRM_{197}-specific IgM serum antibody titers.

PBMCs (Peripheral Blood Mononuclear Cells) collected at Days 1, 8, 36, and 64 will be analyzed using ELISA to measure *C. jejuni* capsule-specific IgG ALS (Antibodies in Lymphocyte Supernatant).

Immunogenicity specimens (serum or PBMCs) collected at supplemental visits because the specimen was not collected at the main study visit will still be considered for inclusion in analyses based on study visit window.

All immunogenicity variables will be reported by the laboratory in $\log_{10}$ titers and will be converted to titers prior to any analysis. The conversion will be done when generating analysis datasets, and the converted result in titers will be rounded to the nearest whole number for analysis and reporting.

5. SAMPLE SIZE CONSIDERATIONS

Sixty (60) participants will be enrolled (20 per cohort). The sample size for each cohort was chosen based on the number of participants deemed appropriate for a first-in-human Phase 1 study. Given the small number of participants per group, the precision of our estimate for adverse events is limited. For example, using an exact binomial interval for no observed adverse events within the 10 participants per group yields a 95% confidence interval (CI) of 0-31% (Clopper-Pearson) (Table 3). Follow-on studies evaluating seemingly safe and immunogenic doses will be required with larger numbers of volunteers in order to better define the safety profile.

6. GENERAL STATISTICAL CONSIDERATIONS

6.1. General Principles

Continuous variables will be summarized using appropriate descriptive statistics such as n (non-missing sample size), mean/geometric mean, standard deviation, median, maximum, and minimum. The number (n) 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 group and participant, and when appropriate by visit number within participant. All summary tables will be structured with a column for each treatment in the order (1µg CJCV2, 1µg CJCV2+ALFQ, 3µg CJCV2, 3µg CJCV2+ALFQ, 10µg CJCV2, 10µg CJCV2+ALFQ) and will be annotated with the total population size relevant to that table/treatment group, including any missing observations.

Confidence intervals for Geometric Mean Titer (GMT) and Geometric Mean Fold-Rise (GMFR) will be calculated using a student's t distribution. Confidence intervals for proportions of participants will be exact CIs using the Clopper-Pearson method.

6.2. Timing of Analyses

The final analysis will be performed after database lock.

6.3. Analysis Populations

The composition of analysis populations, including reasons for participant exclusion will be presented by treatment group and overall (Table 9). A listing of all participants and visits excluded from the analysis populations will be provided (Listing 5).

6.3.1. Safety Population

The Safety Population includes all participants who received at least one dose of study vaccination. Participants will be analyzed according to actual study product received.

6.3.2. Full Immunogenicity Population

The Full Immunogenicity Population consists of all participants who received any study product and contributed both pre- and at least one post-study vaccination blood samples for immunogenicity testing for which valid results were reported. Participants will be analyzed according to actual study product received.

6.3.3. Per Protocol Immunogenicity Population

The Per Protocol (PP) Immunogenicity Population includes all participants in the Full Immunogenicity Population with the following exclusions:

- Data from all available visits for participants found to be ineligible at baseline.
- Data from all visits after major protocol deviations, such as:
  - Receipt of an incorrect study vaccination.
  - Second or third vaccination not received.
  - Second or third vaccination received out of window.
  - Receipt of any of the following:

- Licensed, live vaccine within 30 days of any vaccination.
- Licensed, inactivated vaccine within 14 days of any vaccination.
- Investigational products at any time during study period.

- Data from any visit that occurs out of window.

All protocol deviations will undergo a review prior to database lock, blinded to outcome value to determine if the affected visit and any subsequent visits will be excluded from the PP Immunogenicity Population for the affected participant(s).

6.4. Covariates and Subgroups

The protocol does not define any formal subgroup analyses, and the study is not adequately powered to perform subgroup analyses.

6.5. Missing Data

All attempts will be made to collect all data per protocol. As missing data are expected to be minimal, no imputation will be performed for missing values. Any data point that appears to be erroneous or inexplicable based on clinical judgment will be investigated as a possible outlier. If data points are identified as outliers, sensitivity analyses will be performed to examine the impact of including or excluding the outliers. Any substantive differences in these analyses will be reported.

All immunogenicity variables have a lower limit of quantification (LLOQ). Results that are <LLOQ will be imputed as the limit of detection (LOD) in calculations of summary statistics in tabular and graphical displays. The CRM_{197}-specific IgG and IgM assays have a 3-fold titration series, so the imputed value will be LOD = 1/3*LLOQ. The *C. jejuni* capsule-specific serum IgG and IgM and ALS IgG assays have a 2-fold titration series, so the imputed value will be LOD = ½*LLOQ. Imputed values will be rounded to the nearest whole number for consistency with conversion of results from $\log_{10}$ titer to titer. The number of results <LLOQ will be reported in tabular summaries.

Immune Response	LLOQ		
	Log_{10} Titer	Titer	Imputed Titer when <LLOQ
C. Jejuni Capsule-specific IgG Serum Antibody	2.30	200	100
C. Jejuni Capsule-specific IgM Serum Antibody	2.30	200	100
CRM_{197}-specific IgG Serum Antibody	3.00	1000	333
CRM_{197}-specific IgM Serum Antibody	2.00	100	33
C. Jejuni Capsule-specific IgG ALS Antibody	0.70	5	3

6.6. Interim Analyses and Data Monitoring

No formal statistical interim analysis based on the safety data is planned. The SRC will review safety data through seven days after the last sentinel participant is vaccinated before proceeding to vaccinate additional participants in each cohort. The SRC will review safety data, which may include solicited and unsolicited AE/SAEs, concomitant medications, clinical laboratory values, vital signs, and any physical examinations, through Day 64 for each cohort prior to dose escalation.

No interim immunogenicity review is planned.

6.7. Multicenter Studies

Not applicable. This is a single center study.

6.8. Multiple Comparisons/Multiplicity

The primary outcome is descriptive. No testing or adjustments for multiple testing are planned.

7. STUDY PARTICIPANTS

7.1. Disposition of Participants

Table 11 will present a summary of the reasons that participants were screened but not enrolled.

The composition of analysis populations, including reasons for participant or visit exclusion, by treatment group, will be presented in Table 9.

The disposition of participants in the study including the number of participants screened, enrolled/randomized, receiving vaccination 1, receiving vaccination 2, receiving vaccination 3, completing the final blood draw, completing follow-up, and contributing both pre- and at least 1 post-vaccination blood sample will be tabulated by treatment group (Table 8).

A flow diagram showing the disposition of study participants, adapted from the CONSORT Statement [19] will be included (Figure 1). This figure will present the number of participants screened, enrolled, discontinued, terminated early (including lost to follow-up), and analyzed, by treatment group.

A listing of participants who discontinued vaccinations or terminated from study follow-up and the reason will be included in Listing 2.

7.2. Protocol Deviations

All protocol deviations will be classified as major or minor using the definitions below.

- Major Deviation – A deviation from the Institutional Review Board-approved protocol documents that have, or may have the potential to, negatively impact the rights, welfare, or safety of the participant, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor Deviation – A deviation that does not have the potential to negatively impact the rights, safety, or welfare of participants or others, or the scientific integrity or validity of the study.

Prior to database lock, the SDCC will provide a listing of all protocol deviations with an initial classification of major or minor to DMID who will review and make final determinations to be included in the database lock.

A summary of participant-specific protocol deviations will be presented by deviation category, deviation type, and treatment group for all participants (Table 4). All participant-specific protocol deviations and non-participant-specific protocol deviations will be presented in data listings (Listing 3 and Listing 4, respectively).

8. EFFICACY EVALUATION

Not applicable.

9. SAFETY EVALUATION

9.1. Demographic and Other Baseline Characteristics

All summaries and analysis of safety data will be presented for the Safety Population.

Summaries of categorical (sex, ethnicity, and race) and continuous (age, height, weight, and BMI) demographic variables will be presented by treatment group and overall (Table 12 and Table 13 respectively). Ethnicity is categorized as "Hispanic or Latino" or "Not Hispanic or Latino". In accordance with NIH reporting policy, participants may self-designate as belonging to more than one race or may refuse to identify a race, the latter reflected in the eCRF as "No" to each racial option.

Individual participant demographics and baseline characteristics are included in Listing 6.

9.1.1. Prior and Concurrent Medical Conditions

All current illnesses and past pre-existing medical conditions will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®) dictionary version 27.0 or higher.

Summaries of participants' pre-existing medical conditions will be presented by MedDRA SOC and treatment group (Table 14).

Individual participant listings of pre-existing and concurrent medical conditions will be presented (Listing 7).

9.1.2. Prior and Concomitant Medications

Medications (prescription and over-the counter) and non-study vaccinations taken 30 days prior to enrollment through 28 days after the final vaccination or early termination, whichever occurs first, will be classified using the World Health Organization (WHO) Drug Dictionary (March 2024) Anatomical Therapeutic Chemical (ATC) Classification Levels 1 and 2 and summarized by treatment group and overall (Table 98).

Individual participant listings of all prior and concomitant medications will be presented (Listing 16).

9.2. Measurements of Treatment Compliance

The number participants receiving at least one vaccination, as well as those receiving all scheduled vaccinations, will be presented by treatment group as part of the participant disposition table (Table 8).

Table 10 presents the dates of first vaccination by treatment group and overall. A listing of participants receiving investigational product will be presented in Listing 1.

9.3. Adverse Events

When calculating the incidence of adverse events (i.e., on a per participant basis), each participant will only be counted once per AE using the event with maximum severity and any repetitions of adverse events within a participant will be ignored; the denominator will be the total number of participants receiving the specified vaccination. All unsolicited adverse events reported will be included in Listing 11.

An overall summary of adverse events will be presented in Table 30. A table of all SAEs and non-serious AEs occurring in at least 5% of participants in any treatment group will be presented by MedDRA SOC and PT and treatment group in Table 31.

9.3.1. Solicited Events and Symptoms

Temperatures collected on the Vital Signs eCRF within 7 days following vaccination will be considered towards the solicited AE of fever and will be included in all tables, figures, and listings summarizing solicited AEs.

The number and percentage with 95% CI of participants reporting at least one solicited adverse event of at least mild severity within 7 days following vaccination will be summarized for each solicited symptom, any systemic symptom, any local symptom, and any symptom following each vaccination and following any vaccination for Cohort 1 (Table 32), Cohort 2 (Table 33), and Cohort 3 (Table 34). The 95% CI will be calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option).

For each systemic and local symptom, any systemic symptom, any local symptom, and any solicited symptom, the number and percentage of participants reporting the symptom will be summarized by severity for each day and maximum severity within 7 days after each vaccination for Cohort 1 for vaccination 1 (Table 35), vaccination 2 (Table 36), vaccination 3 (Table 37), and any vaccination (Table 38). Analogous tables for each vaccination and any vaccination will be presented for Cohort 2 (Table 39, Table 40, Table 41, and Table 42) and Cohort 3 (Table 43, Table 44, Table 45, and Table 46). For each event the denominator is the number of participants with non-missing data for the specific event.

The percentage of participants reporting any solicited systemic symptom will be summarized graphically in a bar chart by maximum severity, day post vaccination, and vaccination group for each vaccination (Figure 32, Figure 33, and Figure 34) and for all vaccinations combined (Figure 35). Analogous figures will be presented for any solicited local symptom (Figure 36, Figure 37, Figure 38, and Figure 39).

The percentage of participants experiencing each solicited symptom within 7 days of vaccination will be summarized in a bar chart by maximum severity and treatment group for each vaccination (Figure 40, Figure 41, and Figure 42) and for all vaccinations combined (Figure 43).

All solicited adverse events will be presented by participant in Listing 9 for systemic symptoms and Listing 10 for local symptoms.

9.3.2. Unsolicited Adverse Events

The number and percentage with 95% CI of participants reporting at least one unsolicited adverse event along with the total frequency of unsolicited adverse events will be summarized by MedDRA SOC and PT, vaccination, and treatment group for each cohort (Table 47 for Cohort 1, Table 48 for Cohort 2, and Table 49 for Cohort 3). Denominators for percentages are the number of participants who received the vaccination being summarized.

The number and percentage of participants experiencing unsolicited adverse events along with the frequency of events will be reported by MedDRA SOC and PT, relationship, severity, and treatment group for Cohort 1 for each vaccination (Table 50, Table 51, and Table 52) and any vaccination (Table 53). Analogous tables will be presented for Cohort 2 (Table 54, Table 55, Table 56, and Table 57) and Cohort 3 (Table 58, Table 59, Table 60, and Table 61).

Bar charts will graphically display the frequency of related unsolicited adverse events by MedDRA SOC, severity, and treatment group for each vaccination (Figure 44, Figure 45, and Figure 46) and any vaccination (Figure 47). Analogous bar charts will display the incidence of related unsolicited adverse events (Figure 48, Figure 49, Figure 50, and Figure 51).

Listings of individual events including participant ID, AE description, associated vaccination, onset and duration of AE, severity, relationship (and alternate etiology if Not Related), action taken with study vaccinations, outcome, and MedDRA SOC and PT will be provided for non-serious unsolicited AEs of moderate or greater severity (Table 63).

All reported unsolicited adverse events will be presented in Listing 11.

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

The following listings will be presented including participant ID, AE description, associated vaccination, AE onset and duration, reason reported as an SAE (for SAEs only), severity, relationship to study vaccine (and alternative etiology if Not Related), action taken with study vaccinations, outcome, and MedDRA SOC and PT:

- Deaths and other Serious Adverse Events (Table 62).
- Medically Attended Adverse Events (MAAEs), New Onset Chronic Medical Conditions (NOCMCs), and Potentially Immune-Mediated Medical Conditions (PIMMCs) (Table 64).

9.5. Pregnancies

For any participants in the Safety population who become pregnant during the study, every attempt will be made to follow these participants to completion of pregnancy to document the outcome, including information regarding any complications with pregnancy and/or delivery. Listings of all pregnancies and outcomes will be presented (Listing 17, Listing 18, Listing 19, Listing 20, and Listing 21).

9.6. Clinical Laboratory Evaluations

Laboratory AEs will be graded according to the scale presented in Table 7. Chemistry parameters will include creatinine, ALT, total bilirubin, sodium, and potassium. Hematology parameters will include Hgb, WBC, ANC, and platelets.

All chemistry results for participants with at least one abnormal chemistry result will be listed in Table 65. An analogous table for participants with at least one abnormal hematology result will be listed in Table 66.

The distribution of laboratory results by time point, treatment group, relationship (Total and Related), and severity will be presented for any chemistry parameter (Table 67) and for each parameter (Table 68, Table 69, Table 70, Table 71, and Table 72). Analogous results will be presented for any hematology parameter (Table 79) and for each hematology parameter (Table 80, Table 81, Table 82, and Table 83).

Descriptive statistics including mean, standard deviation, median, minimum, and maximum will be summarized by time point and treatment group for each chemistry parameter (Table 73, Table 74, Table 75, Table 76, Table 77, and Table 78) and each hematology parameter (Table 84, Table 85, Table 86, Table 87, and Table 88); the change from baseline values will also be summarized for post-baseline time points.

Listing 12 and Listing 13 will provide a complete listing of individual clinical laboratory results with applicable reference ranges for chemistry and hematology results respectively.

9.7. Vital Signs and Physical Evaluations

Vital sign measurements will include systolic blood pressure, diastolic blood pressure, pulse, and oral temperature. Vital signs will be assessed at screening (Day -30 to -2), Day 1, Day 8, Day 29, Day 36, Day 57,

Day 64, Day 85, and Day 113 for all Cohorts. Cohort 1 was enrolled and completed follow-up under protocol v4.0 (25MAY2022) which also required collection of vital signs at Day 3, Day 15, Day 31, Day 43, Day 59, and Day 71; in the later versions of the protocol followed by Cohorts 2 and 3, vital signs were only collected on these days if indicated. The tables and listing described in this section will only include vital signs collected in clinic on the Vital Signs eCRF. Vital Signs will be graded according to the scale in Table 6.

Vital signs will be tabulated by severity, time point, and treatment group for any assessment (Table 89) and for each assessment (Table 90, Table 91 , Table 92, and Table 93). Summary statistics of vital signs will be presented for each assessment by time point and treatment group (Table 94, Table 95, Table 96, and Table 97). All vital signs will be listed by participant and time point (Listing 14).

An abbreviated physical examination will be performed at screening (Day -30 to -2), and targeted physical exams will be performed as indicated at subsequent visits. The following body systems will be assessed in the abbreviated physical exam: general appearance, skin, head and neck, lungs, heart, liver, spleen, extremities, musculoskeletal and lymph nodes; the targeted physical exam will only include the relevant body systems. All abnormal findings will be listed by participant and time point (Listing 15).

9.8. Concomitant Medications

Concomitant medications will be coded to the ATC classification using the WHO Drug Dictionary. The use of prior and concomitant medications taken during the study will be recorded on the eCRFs. A by-participant listing of concomitant medication use will be presented (Listing 16). The use of concomitant medications during the study will be summarized by ATC Level 1, ATC2 Level 2 and treatment group for the Safety population (Table 98).

9.9. Other Safety Measures

Not applicable.

10. PHARMACOKINETICS

Not applicable.

11. IMMUNOGENICITY EVALUATION

All immunogenicity analyses will be performed in the Full Immunogenicity Population and the PP Immunogenicity Population.

11.1. Primary Immunogenicity Analyses

There are no primary immunogenicity endpoints.

11.2. Secondary Immunogenicity Analyses

The *C. jejuni* capsule-specific IgG serum antibody titers and FR (for post-baseline time points) will be summarized using a geometric mean with 95% CI, minimum, and maximum for each visit and for peak titer by treatment group (Table 15 for the Full Immunogenicity Population and Table 16 for the PP Immunogenicity Population); the percentage of responders with 95% CI will also be presented for post-baseline time points.

Graphical presentations of immune response by treatment group will include reverse cumulative distribution curves (Figure 2 for the Full Immunogenicity Population and Figure 3 for the PP Immunogenicity Population) and longitudinal presentation of GMTs with 95% CI (Figure 12 for the Full Immunogenicity Population and Figure 13 for the PP Immunogenicity Population).

11.3. Exploratory Immunogenicity Analyses

The CRM_{197}-specific IgG serum antibody titers and FR (for post-baseline time points) will be summarized using a geometric mean with 95% CI, minimum, and maximum for each visit and for peak titer by treatment group (Table 17 for the Full Immunogenicity Population and Table 18 for the PP Immunogenicity Population); the percentage of responders with 95% CI will also be presented for post-baseline time points.

Analogous tables summarizing titers, FR, and responders by visit and treatment group will be presented for *C. jejuni* capsule-specific IgG ALS (Table 19 for the Full Immunogenicity Population and Table 20 for the PP Immunogenicity Population), *C. jejuni* capsule-specific IgM serum antibodies (Table 21 for the Full Immunogenicity Population and Table 22 for the PP Immunogenicity Population), and CRM_{197}-specific IgM serum antibodies (Table 23 for the Full Immunogenicity Population and Table 24 for the PP Immunogenicity Population).

Graphical presentations of immune response by treatment group and time point will include reverse cumulative distribution curves (Figure 4, Figure 5, Figure 6, Figure 7, Figure 8, Figure 9, Figure 10, and Figure 11) and longitudinal presentation of GMTs with 95% CI (Figure 14, Figure 15, Figure 16, Figure 17, Figure 18, Figure 19, Figure 20, and Figure 21).

11.4. Additional Immunogenicity Analyses

A listing of all individual immunogenicity results will be presented by treatment group, participant ID, planned time point, and actual study day in Listing 8.

The timing of the maximum titer result for each participant will be summarized by immune response and treatment group (Table 25 for the Full Immunogenicity Population and Table 26 for the PP Immunogenicity Population). If a participant has more than 1 time point at their maximum value, they will be classified using the earlier time point.

Dose verification assays performed during the study showed that some study product preparations did not fall within the acceptable range of the target dose of CJCV2. The dose verification assays were performed on three aliquots of the prepared study product (except for the sentinels in Cohort 3 which only had one aliquot tested), so the results are only specific to the preparation (denoted by date of preparation) and not individual participants. Thus, the average of all aliquots tested from a preparation will be used as an estimate of the dose that all participants who were vaccinated on the day of the preparation received. The estimated dose received (based on the dose verification assay) will be summarized by vaccination and treatment group (i.e., the planned dose and study product) for the Safety Population (Table 27).

To assess the relationship between estimated dose received (based on the dose verification assay results) and immune response, a set of correlation analyses will be performed. For each immune response and vaccination, the spearman correlation between the cumulative estimated dose of CJCV2 received and the maximum immune response titer measured for that cumulative dose will be calculated for all participants receiving CJCV2 alone across all cohorts (i.e., regardless of the planned CJCV2 dose) and for all participants receiving CJCV2+ALFQ across all cohorts (i.e., regardless of the planned CJCV2 dose) for each immune response in both the Full Immunogenicity Population (Table 28) and the PP Immunogenicity Population (Table 29).

The immune responses that will be analyzed are *C. jejuni* capsule-specific IgG ALS antibody titer, *C. jejuni* capsule-specific IgG serum antibody titer, CRM_{197}-specific IgG serum antibody titer, *C. jejuni* capsule-specific IgM serum antibody titer, and CRM_{197}-specific IgM serum antibody titer. Because the ALS assay is only performed once between each vaccination, the correlation will use the immune response measured 7 days post the applicable vaccination (Study Days 8, 36, and 64 for each vaccination respectively). The correlations involving the serum immune responses will use the maximum titer measured at Day 8 or 29 for Vaccination 1, Study Day 36 or 57 for Vaccination 2, and Study Day 64, 85, or 113 for Vaccination 3. In alignment with the analysis population definitions, if a participant does not receive a third vaccination, their available data will still be included in the "Vaccination 3" panels for the Full Immunogenicity Population but not for the PP Immunogenicity Population.

A scatterplot of the cumulative dose received and *C. jejuni* capsule-specific IgG ALS antibody titer with Spearman correlation coefficient and 95% CI will be presented by vaccination and ALFQ status (Figure 22 for the Full Immunogenicity Population and Figure 23 for the PP Immunogenicity Population). Analogous figures will be presented for the remaining immune responses for the Full Immunogenicity Population (Figure 24, Figure 26, Figure 28, and Figure 30) and the PP Immunogenicity Population (Figure 25, Figure 27, Figure 29, and Figure 31). The two-sided 95% CI will be calculated using Fisher's Z-transformation.

12. OTHER ANALYSES

Not applicable.

13. REPORTING CONVENTIONS

Unless stated otherwise, the following reporting conventions will be used. P-values ≥0.001 and ≤0.999 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001". 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. Proportions will be presented as 2 decimal places; values greater than zero but <0.01 will be presented as "<0.01". Percentages will be reported to the nearest whole number; values greater than zero but < 1% will be presented as "<1"; values greater than 99% but less than 100% will be reported as ">99". Confidence intervals will be reported to the same number of decimal places as the point estimate. Estimated parameters, not on the same scale as raw observations (e.g., regression coefficients) will be reported to 3 significant figures.

14. TECHNICAL DETAILS

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

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

- This is a Phase 1 study and is not designed to test any formal statistical hypotheses. As such, the Fisher's Exact tests comparing the rates of solicited and unsolicited AEs between the CJCV2 and CJCV2+ALFQ groups within a dose cohort have been removed; we are unlikely to gain any useful information from these tests given the small sample sizes and the multiple comparisons that would be introduced.
- After receiving the dose verification results but before database lock and unblinding, additional analyses to look at the correlation between estimated CJCV2 dose received and immune responses were added. The added tables are Table 28 and Table 29; the added figures start at Figure 22 and end at Figure 31; additionally, the estimated doses received will be summarized by vaccination and treatment group (Table 27) and listed by participant for each vaccination (Listing 1).
- The modified Intention to Treat (mITT) analysis population described in the protocol has been renamed to the "Full Analysis Population" to more accurately describe the population; there are no changes to the definition of what will be included or excluded from this population.

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17. LISTING OF TABLES, FIGURES, AND LISTINGS

Table, figure, and listing shells are presented in Appendices 1, 2, and 3.

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9.1 Overall Study Design and Plan Description

Table 1: Study Design

Cohort [a]	Group [b]	N	CJCV2 (µg)	ALFQ
1	Sentinel 1-A [c]	3	1	0
	Sentinel 1-B [c]	3	1	200 µg 3D-PHAD®, 100 µg QS-21
	1-A	7	1	0
	1-B	7	1	200 µg 3D-PHAD®, 100 µg QS-21
2	Sentinel 2-A [c]	3	3	0
	Sentinel 2-B [c]	3	3	200 µg 3D-PHAD®, 100 µg QS-21
	2-A	7	3	0
	2-B	7	3	200 µg 3D-PHAD®, 100 µg QS-21
3	Sentinel 3-A [c]	3	10	0
	Sentinel 3-B [c]	3	10	200 µg 3D-PHAD®, 100 µg QS-21
	3-A	7	10	0
	3-B	7	10	200 µg 3D-PHAD®, 100 µg QS-21

Notes: Participants will receive vaccinations on study days 1, 29, and 57.
[a] SRC Review (PI, Medical Officer, Medical Monitor) through the final vaccine reactogenicity period for each cohort prior to dose escalation.
[b] Sentinels in each cohort will be randomized 1:1 in a blinded fashion to receive CJCV2 with or without ALFQ. Sentinels will be dosed at least 2 hours apart with no more than 2 sentinels per day.
[c] SRC Review (PI, Medical Officer, Medical Monitor) 7-9 days after the first dose. SRC review after second and third doses in Sentinel groups will be completed only if a stopping rule is met.

9.5.1 Immunogenicity and Safety Measurements Assessed and Flow Chart

Table 2: Schedule of Study Procedure

Study Visit [o]	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	U/S[n]	E/T
Visit Type- Clinic	x	x		x		x		x		x		x		x	x			x	x
Visit Type, Clinic or Virtual			x		x		x		x		x		x						
Visit Type- Safety Communication [q]																x	x		
Study Day	-30 to -2	1	3	8	15	29	31	36	43	57	59	64	71	85	113	240	420		
Visit Window [n]			±1	+1	±2	+2	±1	+1	±2	+2	±1	+1	±2	±2	±4	±7	±7		
Informed Consent [a]	x																		
Vaccination		x				x				x									
Demographics	x																		
Medical History [b]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x
Concomitant Medication Review [c]	x	x	x	x	x	x	x	x	x	x	x	x	x	x				x	x
Adverse Event Assessment [d, e]		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Counsel on avoidance of pregnancy [p]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x				
Physical Exam [f]	x	x		x		x		x		x		x		x	x			x	x
Vital signs (BP, HR, Temp) [g]	x	x		x		x		x		x		x		x	x			x	x
Height & Weight	x																	x	
Review Eligibility	x	x																	
Urine Pregnancy Test [h, i]	x	x				x				x				x	x			x	x
Urine Dipstick for protein	x																	x	
Urine Opiate Test	x																	x	
Anti-HIV-1/2, HbsAg, Anti-HCV	x																	x	
HLA-B27	x																		
Hematology & Chemistry [j]	x			x				x				x						x	x
Reactogenicity Assessment [k]		x				x				x								x	

Study Visit [o]	**00**	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**U/S[n]**	**E/T**
E-Memory Aid [l]		x	x	x		x	x	x		x	x	x						x	
Study Vaccination Site Examination		x	x	x		x	x	x		x	x	x						x	
Serum (Serology)		x		x		x		x		x		x		x	x			x	x
Blood (PBMCs) for ALS		x		x				x				x						x	
Blood (PBMCs) for Secondary Research		x		x		x		x		x		x		x	x			x	x
Serum for Secondary Research		x		x		x		x		x		x		x	x			x	x
Stool for Secondary Research [m]		x		x				x				x						x	x
Approx. blood mL by day	37	100		70		40		70		40		70		40	40			40	40

[a] Prior to study procedures.
[b] Complete medical history will be obtained by interview of participants at the screening visit and will be updated on Day 1 prior to the first study vaccination. Interim medical history will be obtained by interview of participants at follow-up visits after the first study vaccination. Contraception history will be collected for females of childbearing potential.
[c] All current medications and medications taken within 30 days prior to signing the ICF. Concomitant medications taken within 30 days of enrollment through 28 days post last vaccination are collected in Advantage eClinical®.
[d] AEs will be assessed through 28 days post last vaccination. SAEs will be followed throughout the study duration.
[e] Unsolicited AEs including MAAEs, NOCMCs, PIMMCs, and SAEs will be collected from participants throughout their period of study participation and SAE to include concomitant medication(s) taken for these events.
[f] An abbreviated physical examination will be performed at screening. A targeted physical examination may be performed at subsequent visits, if indicated based on review of medical history and any updates obtained by interview of participants.
[g] Participants must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.
[h] Prior to vaccination
[i] A urine pregnancy test will be performed within 24 hours prior to study vaccinations and results must be negative and known prior to each study vaccination.
[j] Hematology and Chemistry tests include WBC, Hgb, platelet count, ANC, sodium, potassium, creatinine, T. bili, ALT.
[k] Reactogenicity assessments will occur prior to and ≥ 30 minutes post vaccination.
[l] E-memory aid tools and education will be provided on the days of vaccination. E-memory aid review will occur 48 hours and 7 days post vaccination.
[m] Stool kits will be provided during the visits preceding expected stool collection days.
[n] Unscheduled study (U/S) events and Early Termination (E/T) events to occur as indicated
[o] Visit Window to be initiated at Day 1 of each vaccination day.
[p] Counseling on avoidance of pregnancy will be performed on females of childbearing potential.
[q] Safety Communication follow up visits may occur via phone or email communication

9.7.1 Sample Size

Table 3: Sample Size/Probability Estimates

N per Treatment Group	No observed AEs 95% CI
10	0-31%

10.2 Protocol Deviations

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

[Implementation Note: Only include categories and deviation types with a count >0. Only include the "Any type" row for a category if there is more than 1 distinct deviation type reported in the category. Only include participant-specific deviations.]

Category	Deviation Type	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
		n	m	n	m	n	m	n	m	n	m	n	m	n	m
Major Deviations[a]															
[Category 1]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Category 2]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Category 3]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Minor Deviations															
[Category 1]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Category 2]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Category	Deviation Type	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
		n	m	n	m	n	m	n	m	n	m	n	m	n	m
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Category 3]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
All Deviations															
[Category 1]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Category 2]	Any type	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 2]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	[Type 3]	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: N = Number of participants enrolled.
n = Number of participants reporting specified deviation; a participant is only counted once per deviation type.
m = Number of deviations.
[a] A deviation is classified as major if it has the potential to negatively impact the rights, welfare, or safety of the participant or to substantially negatively impact the scientific integrity or validity of the study.

12.2.2 Displays of Adverse Events

Table 5: Solicited Adverse Event Grading Scale

Injection Site Reaction	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Pain – experienced without touching the injection site (spontaneous discomfort)	Participant is aware of pain, but it does not interfere with daily activity, **and** if pain medication is used, it is Over the Counter (OTC) and used for less than 24 hours	Participant is aware of pain; there is interference with daily activity **or** OTC pain medication is used for more than 24 hours	Participant is aware of pain, **and** it prevents daily activity or pain requires prescription medication
Tenderness-experienced with touching the injection site	Participant is aware of pain, but it does not interfere with daily activity, **and** if pain medication is used, it is Over the Counter (OTC) and used for less than 24 hours	Participant is aware of pain; there is interference with daily activity **or** OTC pain medication is used for more than 24 hours	Participant is aware of pain, **and** it prevents daily activity or pain requires prescription medication
Ecchymosis (Bruising)[a]	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Erythema (Redness)[a]	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Induration (Hardness)/Edema (Swelling)[a]	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Injection Site Reaction	**Small**	**Medium**	**Large**
Ecchymosis (Bruising)[b]	<20 mm	20 mm – 50 mm	>50 mm
Erythema (Redness)[b]	<20 mm	20 mm – 50 mm	>50 mm
Induration (Hardness)/Edema (Swelling)[b]	<20 mm	20 mm – 50 mm	>50 mm
Systemic	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Feverishness	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Fatigue	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Malaise	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Myalgia[c]	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Arthralgia[c]	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity

Injection Site Reaction	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Headache	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity or headache requires prescription medication
Nausea	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity or nausea requires prescription medication
Vomiting	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity or vomiting requires prescription medication
Systemic (Quantitative)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Fever[d] – oral[e]	38.0°C – 38.4°C 100.4°F – 101.1°F	38.5°C – 38.9°C 101.2°F – 102.0°F	>38.9°C >102.0°F

Notes:
[a] Will also be measured in mm but size will not be used as halting criteria.
[b] Will not be used as halting criteria.
[c] Not at injection site.
[d] A fever can be considered not related to the study product if an alternative etiology can be documented.
[e] Oral temperature assessed on Day 1 prior to the first study vaccination will be considered as baseline. Participants must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.

Table 6: Vital Signs Grading Scale

Measurement	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Tachycardia	101 – 115 bpm	116 – 130 bpm	> 130 bpm or ventricular dysrhythmias
Bradycardia	45 – 49 bpm	40 – 44 bpm	< 40 bpm
Systolic Hypertension	141 – 150 mmHg	151 – 160 mmHg	> 160 mmHg
Systolic Hypotension	85 – 89 mmHg	80 – 84 mmHg	< 80 mmHg
Diastolic Hypertension	91 – 95 mmHg	96 – 100 mmHg	> 100 mmHg
Diastolic Hypotension	50 – 54 mmHg	45 – 49 mmHg	< 45 mmHg
Oral Temperature[a]	38.0°C – 38.4°C 100.4°F – 101.1°F	38.5°C – 38.9°C 101.2°F – 102.0°F	>38.9°C >102.0°F

Note: Vital signs measurements that meet these grading criteria and represent a worsening of condition from baseline are reported as unsolicited adverse events.
[a] Oral temperatures assessed from the time of vaccination through 7 days post vaccination for each vaccination will be reported as reactogenicity events rather than as unsolicited adverse events.

12.4.1 Individual Laboratory Measurements and Abnormal Laboratory Values

Table 7: Laboratory Adverse Event Grading Scale

Laboratory	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Sodium, low, mEq/L	132 – 135	130 – 131	<130
Sodium, high, mEq/L	146 – 147	148 – 149	150 or greater
Potassium, high, mEq/L	5.2 – 5.3	5.4 – 5.5	>5.5
Potassium, low, mEq/L	3.3 – 3.4	3.1 – 3.2	<3.1
Creatinine, high mg/dL (female)	1.0 - 1.1	1.2 – 2.0	>2
Creatinine, high mg/dL (male)	1.2 - 1.3	1.4 – 2.0	>2
Liver Function Tests (ALT) increase by factor	>1.0-2.5 x ULN	>2.5-5.0 x ULN	>5.0 x ULN
Total bilirubin	>1.0-1.5 x ULN	>1.5-2.0 x ULN	>2.0 x ULN
Hgb (female), low g/dL	10.9 - 11.6	9.4 - 10.8	≤9.3
Hgb (male), low g/dL	13.1 - 13.2	12.5 - 13.0	≤12.4
WBC, increase, cells, x 10^3u/L	>11.1 - ≤15.0	>15 - ≤ 20	>20.0
WBC, decrease, cells, x 10^3u/L	2.5 - <4.4	1.5 - <2.5	<1.5
ANC, x 10^3u/L	1.2 - <1.7	0.9 - <1.2	<0.9
Platelets, decrease, cells/mm^3	124,000-<134,000	100,000<124,000	<100,000
Urine protein	Trace	1+	2+
Note: ULN is the upper limit of the normal range.			

14.1 Description of Study Participants

14.1.1 Disposition of Participants

Table 8: Participant Disposition by Treatment Group

Participant Disposition	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Screened	--	--	--	--	--	--	--	--	--	--	--	--	x	--
Enrolled/Randomized	x	100	x	100	x	100	x	100	x	100	x	100	x	100
Received First Vaccination	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Received Second Vaccination[a]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Received Third Vaccination[a]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Final Blood Draw (Study Day 113)[a]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Follow-up (Study Day 420)[a]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Contributed both pre- and at least one post-study vaccination blood samples[b]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Note: N = Number of participants enrolled.
[a] Refer to Section 16.2.1 for reasons participants discontinued or terminated early.
[b] Refer to Section 16.2.3 for reasons participants are excluded from the Analysis populations.

Table 9: Analysis Populations by Treatment Group

[Implementation Note: For the Full and Per Protocol Immunogenicity Populations, include a row for each exclusion reason with a count > 0; if there are no exclusions, the applicable "Any Reason" row should be included and cells marked with a "-" to indicate 0 participants were excluded. If there is only one distinct reason for exclusion in an analysis population, then only include the "Any Reason" row but replace "Any Reason" with the reason.]

Analysis Population	Participant Status[a]	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Safety Population	Included	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Excluded: Did not receive any study vaccine	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Full Immunogenicity Population	Included in at least 1 time point	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Excluded from all time points: Any Reason	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Did not receive any study vaccine	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Did not contribute pre- and at least one post-study vaccination blood samples	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Excluded from individual time points: Any Reason	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Per Protocol Immunogenicity Population	Included in at least 1 time point	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Excluded from all time points: Any Reason	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Analysis Population	Participant Status[a]	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Excluded from individual time points: Any Reason	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[Reason 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Note: N = Number of participants enrolled.
[a] A participant may only be counted in one reason for the "Excluded from all time points" status. A participant may be counted in more than one reason for the "Excluded from individual time points" status but is only counted once in each reason. The full list of exclusions by participant is in Section 16.2.3.

Table 10: Dates of First Vaccination by Treatment Group

[Implementation Note: Each row below the "Total" row will be one-month increments.]

Dates of First Vaccination	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)	All Participants (N=X)
Total (Entire period of enrollment)	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY [categorize based on length of enrollment period]	x	x	x	x	x	x	x
…	x	x	x	x	x	x	x
…	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x
Note: N = Number of participants in the Safety Population.							

Table 11: Ineligibility Summary of Screen Failures

[Implementation Note: Include a row for each inclusion criterion not met, exclusion criterion not met, and reason eligible but not enrolled with a count > 0. Only include the "Any [X]" row if there is > 1 distinct criterion/reason in a given category. Sort the specific reasons by descending frequency and then alphabetically if there are ties. Participants who are eligible but are not enrolled will be counted as screen failures.]

Disposition Category	Inclusion/Exclusion Criterion or Reason for Not Enrolling	n[a]	%[b]
Screen failure	Any reason	x	100
Did not meet inclusion criteria	Any inclusion criterion	x	xx
	[inclusion criterion 1]	x	xx
	[inclusion criterion 2]	x	xx
	[inclusion criterion 3]	x	xx
Met exclusion criteria	Any exclusion criterion	x	xx
	[exclusion criterion 1]	x	xx
	[exclusion criterion 2]	x	xx
	[exclusion criterion 3]	x	xx
Eligible but not enrolled	Any reason	x	xx
	[Reason 1]	x	xx
	[Reason 2]	x	xx

[a] More than one criterion may be marked per participant.
[b] Denominator for percentages is the total number of screen failures.

14.1.2 Demographic Data by Study Group

Table 12: Summary of Categorical Demographic and Baseline Characteristics by Treatment Group, All Enrolled Participants

Variable	Characteristic	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants(N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sex	Male	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Female	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Ethnicity	Not Hispanic or Latino	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Hispanic or Latino	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Not Reported	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Unknown	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Race	American Indian or Alaska Native	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Asian	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Native Hawaiian or other Pacific Islander	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Black or African American	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	White	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Multi-Racial	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Unknown	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Note: N = Number of participants enrolled.															

Table 13: Summary of Continuous Demographic and Baseline Characteristics by Treatment Group, All Enrolled Participants

[Implementation Note: If any characteristic is missing for any participant, include a statistic row for "n" and add the footnote, "n = Number of participants enrolled with a measurement available."]

Variable	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)	All Participants (N=X)
Age (years)	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Standard Deviation	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum	xx	xx	xx	xx	xx	xx	xx
	Maximum	xx	xx	xx	xx	xx	xx	xx
Height (cm)	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Weight (kg)	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
BMI (kg/m^2)	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Note: N = Number of participants enrolled.

14.1.3 Prior and Concurrent Medical Conditions

Table 14: Summary of Participants with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group

MedDRA System Organ Class (SOC)	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[SOC 1]														
[SOC 2]														
[SOC 3]														
[SOC 4]														

Notes: N = Number of participants in the Safety Population.
A participant can only be counted once per SOC.

14.2 Immunogenicity Data

Table 15: *C. jejuni* Capsule-specific IgG Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, Full Immunogenicity Population

[Implementation Note: For similar tables using the PP Immunogenicity Population, update the footnotes to "Per Protocol Immunogenicity Population" instead of "Full Immunogenicity Population". For the "Post Vaccination Peak Titer" row, all valid results included in the applicable analysis population will be considered (i.e., results from visits that are excluded from the PP Immunogenicity Population will not be considered towards the "Post Vaccination Peak Titer" for the PP Immunogenicity Population). Individual FR values will be reported to 1 decimal place (i.e., for the Min and Max); the GMFR and 95% CI will be presented to 2 decimal places. The percentage of responders and 95% CI will be reported to 1 decimal place.]

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Pre-Vaccination 1 (Study Day 1)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
7 Days Post Vaccination 1 (Study Day 8)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Pre-Vaccination 2 (Study Day 29)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
7 Days Post Vaccination 2 (Study Day 36)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Pre-Vaccination 3 (Study Day 57)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
7 Days Post Vaccination 3 (Study Day 64)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
28 Days Post Vaccination 3 (Study Day 85)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
56 Days Post Vaccination 3 (Study Day 113)	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Post Vaccination Peak Titer	n	x	x	x	x	x	x
	Number <LLOQ[a]	x	x	x	x	x	x
	Titer: GM (95% CI)[b]	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)	x.x (x.x, x.x)
	Titer: Min, Max	x, x	x, x	x, x	x, x	x, x	x, x
	FR: GM (95% CI)[b]	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
	FR: Min, Max	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x	x.x, x.x
	Responders[c] (95% CI)[d]	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

Notes: N = Number of participants in the Full Immunogenicity Population; n = Number of participants in the Full Immunogenicity Population with valid results at the given time point; GM = Geometric Mean; CI = Confidence Interval; Min = Minimum; Max = Maximum; FR = Fold-rise in antibody titer compared to pre-vaccination 1; LLOQ = Lower Limit of Quantification; LOD = Limit of Detection.

[a] Number of participants in the Full Immunogenicity Population whose result was <LLOQ at the given time point; result is imputed as LOD in summary statistics.

[b] 95% confidence interval based on Student's t distribution.

[c] Percentage of participants with FR ≥ 4.

[d] Exact 95% Clopper-Pearson confidence interval.

Tables with similar format:

Table 16: ***C. jejuni*** **Capsule-specific IgG Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, PP Immunogenicity Population**

Table 17: **CRM_{197}-specific IgG Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, Full Immunogenicity Population**

Table 18: **CRM_{197}-specific IgG Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, PP Immunogenicity Population**

Table 19: ***C. jejuni*** **Capsule-specific IgG ALS Results with 95% Confidence Intervals by Time Point and Treatment Group, Full Immunogenicity Population**

[*Implementation Note: Time points included in this table are Study Days 1, 8, 36, and 64.*]

Table 20: ***C. jejuni*** **Capsule-specific IgG ALS Results with 95% Confidence Intervals by Time Point and Treatment Group, PP Immunogenicity Population**

[*Implementation Note: Time points included in this table are Study Days 1, 8, 36, and 64.*]

Table 21: ***C. jejuni*** **Capsule-specific IgM Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, Full Immunogenicity Population**

Table 22: ***C. jejuni*** **Capsule-specific IgM Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, PP Immunogenicity Population**

Table 23: **CRM_{197}-specific IgM Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, Full Immunogenicity Population**

Table 24: **CRM_{197}-specific IgM Serum Antibody Results with 95% Confidence Intervals by Time Point and Treatment Group, PP Immunogenicity Population**

Table 25: Timing of Maximum Titers by Immune Response and Treatment Group, Full Immunogenicity Population

[Implementation Note: Categorize participants based on their maximum response; if participants have the same maximum response at more than 1 time point, use the earliest time point. All valid results included in the applicable analysis population will be considered (i.e., results from visits that are excluded from the PP Immunogenicity Population will not be considered for the PP Immunogenicity Population). Include a row for all time points applicable to the immune response even if all counts are 0; cells with a zero count will display "-".]

Immune Response	Time Point of Maximum Titer	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%
C. jejuni Capsule-specific IgG Serum Antibody	Pre-Vaccination 1 (Study Day 1)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 1 (Study Day 8)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 2 (Study Day 29)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 2 (Study Day 36)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 3 (Study Day 57)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 3 (Study Day 64)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	28 Days Post Vaccination 3 (Study Day 85)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	56 Days Post Vaccination 3 (Study Day 113)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
CRM_{197}-specific IgG Serum Antibody	Pre-Vaccination 1 (Study Day 1)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 1 (Study Day 8)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 2 (Study Day 29)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 2 (Study Day 36)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 3 (Study Day 57)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Immune Response	Time Point of Maximum Titer	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%
	7 Days Post Vaccination 3 (Study Day 64)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	28 Days Post Vaccination 3 (Study Day 85)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	56 Days Post Vaccination 3 (Study Day 113)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
C. jejuni Capsule-specific IgG ALS	Pre-Vaccination 1 (Study Day 1)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 1 (Study Day 8)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 2 (Study Day 36)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 3 (Study Day 64)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
C. jejuni Capsule-specific IgM Serum Antibody	Pre-Vaccination 1 (Study Day 1)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 1 (Study Day 8)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 2 (Study Day 29)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 2 (Study Day 36)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 3 (Study Day 57)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 3 (Study Day 64)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	28 Days Post Vaccination 3 (Study Day 85)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	56 Days Post Vaccination 3 (Study Day 113)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Immune Response	Time Point of Maximum Titer	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%
CRM_{197}-specific IgM Serum Antibody	Pre-Vaccination 1 (Study Day 1)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 1 (Study Day 8)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 2 (Study Day 29)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 2 (Study Day 36)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Pre-Vaccination 3 (Study Day 57)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	7 Days Post Vaccination 3 (Study Day 64)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	28 Days Post Vaccination 3 (Study Day 85)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	56 Days Post Vaccination 3 (Study Day 113)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Notes: N = Number of participants in the Full Immunogenicity Population.
Each participant can only be counted in a single time point for each immune response; participants are counted in the earliest time point their maximum response occurs.

Table with similar format:

Table 26: Timing of Maximum Titers by Immune Response and Treatment Group, PP Immunogenicity Population

[Implementation Note: Update footnotes with "Per Protocol Immunogenicity Population".]

Table 27: Summary Statistics of Estimated CJCV2 Dose Received by Vaccination and Treatment Group, Safety Population

[Implementation Note: Estimated doses are reported as X.XX µg; report Mean, Standard Deviation, and Median to 3 decimal places and Min and Max to 2 decimal places.]

Vaccination	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Vaccination 1	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Vaccination 2	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Vaccination 2, Cumulative Dose	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Vaccination 3	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx

Vaccination	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Vaccination 3, Cumulative Dose	n	x	x	x	x	x	x
	Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx

Notes: N = Number of participants in the Safety Population; n = Number of participants in the Safety Population who received the specified vaccination; Min = Minimum; Max = Maximum.
Dose verification results are estimated for each batch prepared; all participants vaccinated with the same batch have the same estimated CJCV2 dose received for that vaccination.
Estimated doses are reported in µg.

Table 28: Spearman Correlations between Cumulative Estimated Dose of CJCV2 and Immune Response by Vaccination Number and ALFQ Status, Full Immunogenicity Population

[Implementation Note: All valid results included in the applicable analysis population will be considered (i.e., results from visits that are excluded from the PP Immunogenicity Population will not be considered for the PP Immunogenicity Population).]

Immune Response	Statistic	Vaccination 1[a]		Vaccination 2[b]		Vaccination 3[c]	
		CJCV2 (N=X)	CJCV2+ALFQ (N=X)	CJCV2 (N=X)	CJCV2+ALFQ (N=X)	CJCV2 (N=X)	CJCV2+ALFQ (N=X)
C. jejuni Capsule-specific IgG Serum Antibody	n	x	x	x	x	x	x
	Spearman Correlation Coefficient	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	95% CI[d]	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
CRM_{197}-specific Capsule-specific IgG Serum Antibody	n	x	x	x	x	x	x
	Spearman Correlation Coefficient	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	95% CI[d]	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
C. jejuni Capsule-specific IgG ALS	n	x	x	x	x	x	x
	Spearman Correlation Coefficient	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	95% CI[d]	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
C. jejuni Capsule-specific IgM Serum Antibody	n	x	x	x	x	x	x
	Spearman Correlation Coefficient	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	95% CI[d]	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
CRM_{197}-specific Capsule-specific IgM Serum Antibody	n	x	x	x	x	x	x
	Spearman Correlation Coefficient	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
	95% CI[d]	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx

Notes: N = Number of participants with at least one visit post the specified vaccination visit in the Full Immunogenicity Population summed across all cohorts by ALFQ status; n = Number of participants in the Full Immunogenicity Population with valid immunogenicity results included in the correlation.
[a] Results are from Study Day 8 for the ALS assay and the maximum result from Study Days 8 and 29 for serum assays.
[b] Results are from Study Day 36 for the ALS assay and the maximum result from Study Days 36 and 57 for serum assays.
[c] Results are from Study Day 64 for the ALS assay and the maximum result from Study Days 64, 85, and 113 for serum assays.
[d] 95% confidence interval calculated using Fisher's Z transformation.

Table with a similar format:

Table 29: Spearman Correlations between Cumulative Estimated Dose of CJCV2 and Immune Response by Vaccination Number and ALFQ Status, PP Immunogenicity Population

[Implementation Note: Update footnotes for "N" and "n" to "N = Number of participants who received the specified vaccination in the Per Protocol Immunogenicity Population summed across all cohorts by ALFQ status; n = Number of participants in the Per Protocol Immunogenicity Population with valid immunogenicity results included in the correlation.".]

14.3 Safety Data

14.3.1 Displays of Adverse Events

Table 30: Overall Summary of Adverse Events

[Implementation Note: For the severity rows, a participant will only be counted in one severity category and will be categorized by the maximum severity experienced.]

	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
Participants with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one local solicited adverse event[a]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one systemic solicited adverse event[a]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one unsolicited adverse event[b]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Mild (Grade 1)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Moderate (Grade 2)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Severe (Grade 3)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one related unsolicited adverse event[b]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Mild (Grade 1)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Moderate (Grade 2)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Severe (Grade 3)	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one clinical laboratory adverse event[a]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one related clinical laboratory adverse event[a]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one serious adverse event[c,d]	x	x	x	x	x	x	x	x	x	x	x	x	x	x

	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
Participants with	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
At least one related, serious adverse event[c,d]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one adverse event leading to early termination[e]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one medically attended adverse event[d]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one new onset chronic medical condition[d]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one potentially immune mediated medical condition[d]	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: N = Number of participants in the Safety Population.
Participants can only be counted once for each category regardless of the number of events and are categorized by maximum severity.
[a] Collected from vaccination through 7 days post vaccination for each vaccination.
[b] Collected from vaccination through 28 days post vaccination for each vaccination.
[c] A listing of Serious Adverse Events is included in Section 14.3.2.
[d] Collected from the time of first vaccination through 12 months following final vaccination.
[e] As reported on the Adverse Event eCRF.

Table 31: Non-Serious Adverse Events Occurring in At Least 5% of Participants in Any Treatment Group and All Serious Adverse Events by MedDRA System Organ Class and Preferred Term and Treatment Group

[Implementation Note: This table is used to complete the "Other Adverse Event Template" for clinicaltrials.gov reporting. Solicited AEs, unsolicited AEs, and laboratory AEs should be considered for inclusion in this table. Solicited and unsolicited AEs will be considered separately when determining whether the AE meets the 5% criterion and will be reported in separate rows. Solicited AEs (reported on the Treatment Administration Record, Solicited Events Record, or Vital Signs [only temperature within solicited event reporting period] forms) and protocol-defined laboratory parameters (reported on the Local Laboratory Results form) will be included in the systematic collection rows. Any non-serious AEs reported on the Adverse Event form (including graded vital signs and non-protocol defined laboratory parameters) will be included in the non-systematic collection rows. All SAEs should be included in the table, i.e., the 5% criterion does not need to be met for the event to be included in the table. For SAEs and non-serious AEs that were non-systematically collected, an event is defined by each eCRF submitted. For AEs that were systematically collected, an event is defined by occurrence after a single vaccination, i.e., a single participant who received all three vaccinations could contribute up to three events for each symptom/parameter collected. Sort the SOCs by descending incidence (n) and frequency (Events) across all participants (any other ties should be in alphabetical order). Within an SOC, sort the PTs by descending incidence (n) and frequency (Events) across all participants (any other ties should be in alphabetical order).]

Preferred Term	MedDRA System Organ Class	1 µg CJCV2 (N=X)			1 µg CJCV2+ALFQ (N=X)			3 µg CJCV2 (N=X)			3 µg CJCV2+ALFQ (N=X)			10 µg CJCV2 (N=X)			10 µg CJCV2+ALFQ (N=X)			All Participants (N=X)		
		n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events
Serious Adverse Events[a]																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[PT 1]	[SOC 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Etc.]	[Etc.]																					
Other (Non-serious) Adverse Events – Non-systematic Collection																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[PT 1]	[SOC 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[Etc.]	[Etc.]																					
Other (Non-serious) Adverse Events – Systematic Collection																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[PT 1]	[SOC 1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Preferred Term	MedDRA System Organ Class	1 µg CJCV2 (N=X)			1 µg CJCV2+ALFQ (N=X)			3 µg CJCV2 (N=X)			3 µg CJCV2+ALFQ (N=X)			10 µg CJCV2 (N=X)			10 µg CJCV2+ALFQ (N=X)			All Participants (N=X)		
		n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events
[Etc.]	[Etc.]																					

Notes: N = Number of participants in the Safety Population (number of participants at risk); Events = Total frequency of events reported.
Participants can only be counted once per PT.
[a] All SAEs are included in the table; a listing of Serious Adverse Events is included in Section 14.3.2.

14.3.1.1 Solicited Adverse Events

Table 32: Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom, Vaccination, and Treatment Group - Cohort 1

[Implementation Note: This table will summarize all post-vaccination solicited symptoms of at least mild severity regardless of pre-vaccination severity.]

Symptom	Vaccination[a]	1 µg CJCV2				1 µg CJCV2+ALFQ			
		N	n	%	95% CI[b]	N	n	%	95% CI[b]
Any Solicited Symptom	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Systemic Symptoms									
Any Systemic Symptom	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Arthralgia	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Fatigue	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Fever	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Feverishness[c]	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Headache	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx

Symptom	Vaccination[a]	1 µg CJCV2				1 µg CJCV2+ALFQ			
		N	n	%	95% CI[b]	N	n	%	95% CI[b]
Malaise	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Myalgia	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Nausea	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Vomiting	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Local Symptoms									
Any Local Symptom	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Ecchymosis	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Ecchymosis (measurement)	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Erythema	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Erythema (measurement)	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx

Symptom	Vaccination[a]	1 µg CJCV2				1 µg CJCV2+ALFQ			
		N	n	%	95% CI[b]	N	n	%	95% CI[b]
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Induration/Edema	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Induration/Edema (measurement)	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Pain	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx
Tenderness	Vac 1	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 2	x	x	xx	xx, xx	x	x	xx	xx, xx
	Vac 3	x	x	xx	xx, xx	x	x	xx	xx, xx
	Any Vac	x	x	xx	xx, xx	x	x	xx	xx, xx

Notes: N = Number of participants in the Safety Population who received the specified vaccination.
[a] Reported from time of vaccination through 7 days post vaccination.
[b] Exact 95% Clopper-Pearson confidence interval.
[c] Chills/shivering/sweating.

Tables with similar format:

Table 33: Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Vaccination - Cohort 2

Table 34: Number and Percentage of Participants Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Vaccination - Cohort 3

Table 35: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group - Cohort 1, Vaccination 1

[Implementation Note: The "Post Vac" time point is the in-clinic assessment 30 minutes after vaccination, and Day 1 is from the memory aid completed by the participant for the day of vaccination. If there are any time points with at least 1 participant with a symptom that was not assessed, remove (N=X) from the header of each treatment group and add a column labelled "N" before the "None" category for each treatment group. Update the "N =" footnote to "N = Number of participants in the Safety Population who received the specified vaccination and were assessed for the given symptom at the given time point.".]

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any Symptom	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Systemic Symptoms																	
Any Systemic Symptom	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Arthralgia	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Fatigue	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Fever[a]	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Feverishness[b]	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Headache	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Malaise	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Myalgia	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Nausea	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Vomiting	Pre-Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Local Symptoms																	
Ecchymosis	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Ecchymosis (measurement)	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Erythema	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Erythema (measurement)	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Induration/Edema	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Induration/Edema (measurement)	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Pain	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Symptom	Day Relative to Vaccination	1 ug CJCV2 (N=X)								1 ug CJCV2+ALFQ (N=X)							
		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Tenderness	Post Vac	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 3	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 4	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 5	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 6	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 7	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Maximum	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Notes: N = Number of participants in the Safety Population who received the specified vaccination; Vac = Vaccination.
"Pre-Vac" is the assessment prior to vaccination (systemic symptoms only), "Post Vac" is the in-clinic assessment 30 minutes after vaccination; "Day 1" is from the memory aid completed by the participant for the day of vaccination; "Maximum" is the maximum severity reported within 7 days following vaccination.
[a] Fever was only collected for reactogenicity on the memory aid.
[b] Chills/shivering/sweating.

Tables with similar format:

Table 36: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 1, Vaccination 2

Table 37: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 1, Vaccination 3

Table 38: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 1, Any Vaccination

Table 39: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 2, Vaccination 1

Table 40: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 2, Vaccination 2

Table 41: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 2, Vaccination 3

Table 42: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 2, Any Vaccination

Table 43: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 3, Vaccination 1

Table 44: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 3, Vaccination 2

Table 45: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 3, Vaccination 3

Table 46: Number and Percentage of Participants Experiencing Solicited Events by Symptom, Severity, Day Relative to Vaccination, and Treatment Group – Cohort 3, Any Vaccination

14.3.1.2 Unsolicited Adverse Events

Table 47: Summary of Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Vaccination, and Treatment Group – Cohort 1

[Implementation Note: Only include an "Any PT" row for an SOC if there is > 1 distinct PT in the SOC. If a vaccination time point does not have any events in an SOC/PT, then it is not necessary to include a row for that vaccination. Sort the SOCs by descending frequency across the entire cohort based on the "Any Vaccination" time point ("Any SOC" should be first; any other ties should be in alphabetical order). Within an SOC, sort the PTs by descending frequency across the entire cohort based on the "Any Vaccination" time point ("Any PT" should be first; any other ties should be in alphabetical order).]

MedDRA System Organ Class (SOC)	MedDRA Preferred Term (PT)	Vaccination[a]	1 µg CJCV2				1 µg CJCV2+ALFQ			
			N	n	% (95% CI)[b]	Events	N	n	% (95% CI)[b]	Events
Any SOC	Any PT	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
[SOC 1]	Any PT	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
	[PT 1]	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
	[PT 2]	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x

MedDRA System Organ Class (SOC)	MedDRA Preferred Term (PT)	Vaccination[a]	1 µg CJCV2				1 µg CJCV2+ALFQ			
			N	n	% (95% CI)[b]	Events	N	n	% (95% CI)[b]	Events
[SOC 2]	Any PT	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
	[PT 1]	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
	[PT 2]	Vac 1	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 2	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Vac 3	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x
		Any Vac	xx	x	xx (xx, xx)	x	xx	x	xx (xx, xx)	x

Notes: N = Number of participants in the Safety Population receiving the specified vaccination; Events = Total frequency of events reported; MedDRA = Medical Dictionary for Regulatory Activities; Vac = Vaccination.
Participants can only be counted once per PT and vaccination.
[a] Reported from time of vaccination through 28 days post vaccination.
[b] Exact Clopper-Pearson 95% confidence interval.

Tables with similar format:

Table 48: Summary of Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Vaccination, and Treatment Group – Cohort 2

Table 49: Summary of Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Vaccination, and Treatment Group – Cohort 3

Table 50: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 1, Vaccination 1

[Implementation Note: Only include an "Any PT" row for an SOC if it has > 1 distinct PT. Sort the SOCs by descending frequency across the entire cohort based on "Any Severity" with any relationship ("Any SOC" should be first; any other ties should be in alphabetical order). Within an SOC, sort the PTs by descending frequency across the entire cohort based on "Any Severity" and any relationship ("Any PT" should be first; any other ties should be in alphabetical order).]

MedDRA System Organ Class (SOC)	MedDRA Preferred Term (PT)	Severity	1 µg CJCV2 (N=X)				1 µg CJCV2+ALFQ (N=X)			
			Total		Related		Total		Related	
			n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any SOC	Any PT	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
[SOC 1]	Any PT	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
	[PT 1]	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
	[PT 2]	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx

[SOC 2]	Any PT	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
	[PT 1]	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
	[PT 2]	Any Severity	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Mild	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Moderate	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx
		Severe	x (xx)	xx	x (xx)	xx	x (xx)	xx	x (xx)	xx

Notes: N = Number of participants in the Safety Population receiving the specified vaccination; n = Number of participants who experienced an adverse event in the specified SOC, PT, severity, and relationship (participants can only be counted once per PT and relationship and are summarized by maximum severity); Events = Total frequency of events reported; MedDRA = Medical Dictionary for Regulatory Activities.
Details of moderate or severe unsolicited adverse events are listed in Section 14.3.2.

Tables with similar format:

Table 51: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 1, Vaccination 2

Table 52: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 1, Vaccination 3

Table 53: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 1, Any Vaccination

Table 54: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 2, Vaccination 1

Table 55: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 2, Vaccination 2

Table 56: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 2, Vaccination 3

Table 57: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 2, Any Vaccination

Table 58: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 3, Vaccination 1

Table 59: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 3, Vaccination 2

Table 60: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 3, Vaccination 3

Table 61: Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group – Cohort 3, Any Vaccination

14.3.2 Listing of Deaths, Other Serious and Significant Adverse Events

Table 62: Listing of Serious Adverse Events

[Implementation Note: The "Start Day Relative to Vac (Duration)" column will be the day of AE onset with the day of the associated vaccination being Day 1; the duration will be the duration of the AE in days. For the "Reason Reported as an SAE" column, include all reasons selected in the eCRF; if the box for a medically important event not covered by other "serious" criteria is checked, display "Other medically important event: [reason entered by site]". For "If Not Related, Alternate Etiology", concatenate the "If Not Related, is event related to" and the "If Not Related, specify alternative etiology" fields from the Adverse Events eCRF separated by a colon. If there are no comments, include "None" in the comments row. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and AE Number.

If no SAEs are reported, this table will be replaced with text that states, "No Serious Adverse Events have been reported in Protocol 19-0003." There should be a black border around the text, and the text should be a minimum of 9 pt font.]

Adverse Event	Associated Vac No.	Start Day Relative to Vac (Duration)	Day Relative to Vac Event Became Serious	Reason Reported as an SAE	Severity	Relationship to Study Vac (If Not Related, Alternate Etiology)	Action Taken with Study Vaccinations	Participant Discontinued Due to AE?	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX											
	Vac [X]	Day X (Y Days)	X		[Mild, Moderate, Severe]	[Related, Not Related ([alternate etiology])]		[No, Yes]			
Comments:											
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX											
Comments:											
Notes: Vac = Vaccination; No. = Number; SAE = Serious Adverse Event; AE = Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.											

Table 63: Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events

[Implementation Note: The "Start Day Relative to Vac (Duration)" column will be the day of AE onset with the day of the associated vaccination being Day 1; the duration will be the duration of the AE in days. For "If Not Related, Alternate Etiology", concatenate the "If Not Related, is event related to" and the "If Not Related, specify alternative etiology" fields from the Adverse Events eCRF separated by a colon. If there are no comments, include "None" in the comments row. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and AE Number.]

Adverse Event	Associated Vac No.	Start Day Relative to Vac (Duration)	Severity	Relationship to Study Vaccine (If Not Related, Alternate Etiology)	Action Taken with Study Vaccinations	Participant Discontinued Due to AE?	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX									
	Vac [X]	Day X (Y days)	[Mild, Moderate, Severe]	[Related, Not Related ([alternate etiology])		[No, Yes]			
Comments:									
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX									
Comments:									
Notes: Vac = Vaccination; No. = Number; AE = Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.									

Table 64: Listing of Other Significant Adverse Events

[Implementation Note: The "Start Day Relative to Vac (Duration)" column will be the day of AE onset with the day of the associated vaccination being Day 1; the duration will be the duration of the AE in days. For "If Not Related, Alternate Etiology", concatenate the "If Not Related, is event related to" and the "If Not Related, specify alternative etiology" fields from the Adverse Events eCRF separated by a colon. The "PIMMC/NOCMC/MAAE?" column should list all classifications that apply to the AE (separate by commas if more than 1). If there are no comments, include "None" in the comments row. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and AE Number.]

Adverse Event	Associated Vac No.	Start Day Relative to Vac (Duration)	Severity	Relationship to Study Vaccine (If Not Related, Alternate Etiology)	PIMMC, NOCMC, MAAE?	Action Taken with Study Vaccinations	Participant Discontinued Due to AE?	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX										
	Vac [X]	Day X (Y days)	[Mild, Moderate, Severe]	[Related, Not Related ([alternate etiology])	[PIMMC, NOCMC, MAAE]		[No, Yes]			
Comments:										
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX										
Comments:										

Notes: Vac = Vaccination; No. = Number; PIMMC = Potentially Immune-Mediated Medical Condition; NOCMC = New Onset Chronic Medical Condition; MAAE = Medically Attended Adverse Event; AE = Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.

14.3.3 Narratives of Deaths, Other Serious and Significant Adverse Events

(Not included in SAP, but this is a placeholder for the CSR)

14.3.4 Abnormal Laboratory Value Listings (by Participant)

Table 65: Listing of Abnormal Laboratory Results – Chemistry

[Implementation Note: The "Analysis Time Point" column values will use the same format as in summary statistic tables. The "Actual Study Day" column will show the actual day relative to first vaccination where the day of first vaccination is Day 1. Include all chemistry results (i.e., all parameters at all time points) for any participants with at least one abnormal chemistry value. The column for clinical significance will be "N/A" for results within the normal range. The columns for relationship, action taken with study vaccinations, and whether participant was discontinued will be "N/A" for results within the normal range and results prior to the first study vaccination. The footnotes should only include abbreviations appearing in the table. Sort by Treatment Group, Participant ID, Actual Study Day, and Laboratory Parameter. Note that the values in the table are meant to represent the possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Sex	Analysis Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Clinically Significant?	Relationship to Study Vac (If Not Related, Alternate Etiology)	Action Taken with Study Vaccinations	Participant Discontinued Due to Result?
1 µg CJCV2	EHD.XXXXX	Male	Screening (Study Day -30 to -2)	X	ALT (U/L)	X (None)	No	Related		No
1 µg CJCV2+ALFQ		Female	7 Days Post Vaccination 1 (Study Day 8)		Creatinine (mg/dL)	X (ONR)	Yes	Not Related ([alternate etiology])		Yes
3 µg CJCV2			7 Days Post Vaccination 2 (Study Day 36)		Potassium (mEg/L)	X (Mild)	N/A	N/A		N/A
3 µg CJCV2+ALFQ			7 Days Post Vaccination 3 (Study Day 64)		Sodium (mEg/L)	X (Moderate)				
10 µg CJCV2			Unscheduled Visit		T. Bili. (mg/dL)	X (Severe)				
10 µg CJCV2+ALFQ										

Notes: Vac = Vaccination; N/A = Not Applicable; ONR = Outside Normal Range; ALT = Alanine Aminotransferase; T. Bili. = Total Bilirubin; U = Units; L = Liter; mg = milligram; dL = deciliter; mEg = milliequivalent.

Table 66: Listing of Abnormal Laboratory Results – Hematology

[Implementation Note: The "Analysis Time Point" column values will use the same format as in summary statistic tables. The "Actual Study Day" column will show the actual day relative to first vaccination where the day of first vaccination is Day 1. Include all hematology results (i.e., all parameters at all time points) for any participants with at least one abnormal hematology value. The column for clinical significance will be "N/A" for results within the normal range. The columns for relationship, action taken with study vaccinations, and whether participant was discontinued will be "N/A" for results within the normal range and results prior to the first study vaccination. The footnotes should only include abbreviations appearing in the table. Sort by Treatment Group, Participant ID, Actual Study Day, and Laboratory Parameter. Note that the values in the table are meant to represent the possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Sex	Analysis Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Clinically Significant?	Relationship to Study Vac (If Not Related, Alternate Etiology)	Action Taken with Study Vaccinations	Participant Discontinued Due to Result?
1 µg CJCV2	EHD.XXXXX	Male	Screening (Study Day -30 to -2)	X	ANC (10^9/L)	X (None)	No	Related		No
1 µg CJCV2+ALFQ		Female	7 Days Post Vaccination 1 (Study Day 8)		Hgb (g/dL)	X (ONR)	Yes	Not Related ([alternate etiology])		Yes
3 µg CJCV2			7 Days Post Vaccination 2 (Study Day 36)		Platelets (10^9/L)	X (Mild)		N/A		N/A
3 µg CJCV2+ALFQ			7 Days Post Vaccination 3 (Study Day 64)		WBC (10^9/L)	X (Moderate)				
10 µg CJCV2						X (Severe)				
10 µg CJCV2+ALFQ										

Notes: Vac = Vaccination; N/A = Not Applicable; ONR = Outside Normal Range; ANC = Absolute Neutrophil Count; Hgb = Hemoglobin; WBC = White Blood Cells; L = Liter; dL = deciliter; g = grams.

14.3.5 Displays of Laboratory Results

14.3.5.1 Chemistry Results

Table 67: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Any Chemistry Parameter

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point. All "Related" columns for the screening time point will display "N/A" since no study vaccine has been received. If there are no "Related" events for a given table/parameter, remove the "Related" columns from the table, remove "and relationship" from the footnote about counting participants, and add the footnote, "No Related events were reported for [parameter].". Only include "N/A" abbreviation in footnotes if it appears in the table.]

Time Point	Treatment Group	N	Total				Related				Missing
			None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	n
Screening (Study Day -30 to -2)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	Total				Related				Missing
			None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	n
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Notes: N = Number of participants in the Safety Population with a result at the specified time point; N/A = Not Applicable.
Participants are counted once per time point and relationship.
[a] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.

Tables with similar format:

Table 68: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – ALT

Table 69: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Creatinine

Table 70: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Total Bilirubin

Table 71: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity - Potassium

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point. All "Related" columns for the screening time point will display "N/A" since no study vaccine has been received. If there are no "Related" events for a given table/parameter, remove the "Related" columns from the table, remove "and relationship" from the footnote about counting participants, and add the footnote, "No Related events were reported for [parameter].". Only include "N/A" abbreviation in footnotes if it appears in the table.]

			Total							Related							Missing
			None	Mild		Moderate		Severe		None	Mild		Moderate		Severe		
Time Point	Treatment Group	N	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
Screening (Study Day -30 to -2)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	Total							Related							Missing
			None	Mild		Moderate		Severe		None	Mild		Moderate		Severe		
			n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Notes: N = Number of participants in the Safety Population with a result at the specified time point; N/A = Not Applicable.
Participants are counted once per time point and relationship.
[a] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.

Table with similar format:

Table 72: Chemistry Laboratory Results by Time Point, Treatment Group, Relationship, and Severity - Sodium

Table 73: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – ALT

[Implementation Note: Include a statistic row with "Missing" if any results are missing for that time point. Results are reported as XXX U/L; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max.]

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Screening (Study Day -30 to -2)	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
7 Days Post Vaccination 1 (Study Day 8)	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
7 Days Post Vaccination 1 (Study Day 8), Change from Baseline	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
7 Days Post Vaccination 2 (Study Day 36)	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
7 Days Post Vaccination 2 (Study Day 36), Change from Baseline	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
7 Days Post Vaccination 3 (Study Day 64)	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
7 Days Post Vaccination 3 (Study Day 64), Change from Baseline	n	x	x	x	x	x	x
	Mean	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Standard Deviation	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

Notes: N = Number of participants in the Safety Population; n = Number of participants in the Safety Population with a result at the specified time point; Min = Minimum; Max = Maximum.
Statistics other than n are reported as U/L.

Tables with similar format:

Table 74: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – Creatinine, Males

[Implementation Note: Results are reported as X.XX mg/dL; report 3 decimal places for Mean, Standard Deviation, and Median and 2 decimal places for Min and Max. Update the footnote with applicable units.]

Table 75: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – Creatinine, Females

[Implementation Note: Results are reported as X.XX mg/dL; report 3 decimal places for Mean, Standard Deviation, and Median and 2 decimal places for Min and Max. Update the footnote with applicable units.]

Table 76: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – Potassium

[Implementation Note: Results are reported as X.X mmol/L; report 2 decimal places for Mean, Standard Deviation, and Median and 1 decimal place for Min and Max. Update the footnote with applicable units.]

Table 77: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – Sodium

[Implementation Note: Results are reported as XXX mmol/L; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max. Update the footnote with applicable units.]

Table 78: Chemistry Laboratory Summary Statistics by Time Point and Treatment Group – Total Bilirubin

[Implementation Note: Results are reported as X.X mg/dL; report 2 decimal places for Mean, Standard Deviation, and Median and 1 decimal place for Min and Max. Update the footnote with applicable units.]

14.3.5.2 Hematology Results

Table 79: Hematology Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Any Hematology Parameter

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point. All "Related" columns for the screening time point will display "N/A" since no study vaccine has been received. If there are no "Related" events for a given table/parameter, remove the "Related" columns from the table, remove "and relationship" from the footnote about counting participants, and add the footnote, "No Related events were reported for [parameter].". Only include "N/A" abbreviation in footnotes if it appears in the table.]

Time Point	Treatment Group	N	Total				Related				Missing
			None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	n
Screening (Study Day -30 to -2)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	Total				Related				Missing
			None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	n
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Notes: N = Number of participants in the Safety Population with a result at the specified time point; N/A = Not Applicable.
Participants are counted once per time point and relationship.
[a] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.

Tables with similar format:

Table 80: Hematology Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Absolute Neutrophil Count

Table 81: Hematology Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Hemoglobin

Table 82: Hematology Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – Platelets

Table 83: Hematology Laboratory Results by Time Point, Treatment Group, Relationship, and Severity – WBC

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point. All "Related" columns for the screening time point will display "N/A" since no study vaccine has been received. If there are no "Related" events for a given table/parameter, remove the "Related" columns from the table, remove "and relationship" from the footnote about counting participants, and add the footnote, "No Related events were reported for [parameter].". Only include "N/A" abbreviation in footnotes if it appears in the table.]

			Total							Related							Missing
			None	Mild		Moderate		Severe		None	Mild		Moderate		Severe		
Time Point	Treatment Group	N	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
Screening (Study Day -30 to -2)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	Total							Related							Missing
			None	Mild		Moderate		Severe		None	Mild		Moderate		Severe		
			n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Notes: N = Number of participants in the Safety Population with a result at the specified time point; N/A = Not Applicable.
Participants are counted once per time point and relationship.
[a] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.

Table 84: Hematology Laboratory Summary Statistics by Time Point and Treatment Group – Absolute Neutrophil Count

[Implementation Note: Include a statistic row with "Missing" if any results are missing for that time point. Results are reported as XX.XX x10^3/µL; report 3 decimal places for Mean, Standard Deviation, and Median and 2 decimal places for Min and Max.]

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Screening (Study Day -30 to -2)	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
7 Days Post Vaccination 1 (Study Day 8)	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
7 Days Post Vaccination 1 (Study Day 8), Change from Baseline	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
7 Days Post Vaccination 2 (Study Day 36)	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
7 Days Post Vaccination 2 (Study Day 36), Change from Baseline	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
7 Days Post Vaccination 3 (Study Day 64)	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
7 Days Post Vaccination 3 (Study Day 64), Change from Baseline	n	x	x	x	x	x	x
	Mean	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx

Notes: N = Number of participants in the Safety Population; n = Number of participants in the Safety Population with a result at the specified time point; Min = Minimum; Max = Maximum.
Statistics other than n are reported as $x10^3/\mu L$.

Tables with similar format:

Table 85: Hematology Laboratory Summary Statistics by Time Point and Treatment Group – Hemoglobin, Males

[Implementation Note: Results are reported as XX.X g/dL; report 2 decimal places for Mean, Standard Deviation, and Median and 1 decimal place for Min and Max. Update the footnote with applicable units.]

Table 86: Hematology Laboratory Summary Statistics by Time Point and Treatment Group – Hemoglobin, Females

[Implementation Note: Results are reported as XX.X g/dL; report 2 decimal places for Mean, Standard Deviation, and Median and 1 decimal place for Min and Max. Update the footnote with applicable units.]

Table 87: Hematology Laboratory Summary Statistics by Time Point and Treatment Group – Platelets

[Implementation Note: Results are reported as XXX x10^3/µL; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max. Update the footnote with applicable units.]

Table 88: Hematology Laboratory Summary Statistics by Time Point and Treatment Group – WBC

[Implementation Note: Results are reported as X.XX x10^3/µL; report 3 decimal places for Mean, Standard Deviation, and Median and 2 decimal places for Min and Max. Update the footnote with applicable units.]

14.3.6 Displays of Vital Signs

Table 89: Vital Signs by Time Point, Treatment Group, and Severity – Any Assessment

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. If all vital signs are "None" at the Pre-Vaccination 1 (Study Day 1) time point, that time point may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point. For Temperature, only include the temperature measurements taken in-clinic and entered on the Vital Signs eCRF in this table (i.e., do not consider events from the participant's eMemory Aid).]

Time Point	Treatment Group	N	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n
Pre-Vaccination 1 (Study Day 1)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 1 (Study Day 3)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 1 (Study Day 15)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
Pre-Vaccination 2 (Study Day 29)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 2 (Study Day 31)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 2 (Study Day 43)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
Pre-Vaccination 3 (Study Day 57)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 3 (Study Day 59)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 3 (Study Day 71)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
28 Days Post Vaccination 3 (Study Day 85)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
56 Days Post Vaccination 3 (Study Day 113)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[b]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n
Notes: N = Number of participants in the Safety Population with a result at the specified time point. Participants are counted once per time point. [a] Cohort 1 was enrolled and completed follow-up under v4.0 of the protocol which required collection of vital signs at this time point which was not required beginning in v5.0 of the protocol. [b] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.							

Table with similar format:

Table 90: Vital Signs by Time Point, Treatment Group, and Severity – Temperature

[Implementation Note: Only include the temperature measurements taken in-clinic and entered on the Vital Signs eCRF in this table (i.e., do not consider events from the participant's eMemory Aid).]

Table 91: Vital Signs by Time Point, Treatment Group, and Severity – Pulse

[Implementation Note: Participants will be counted as "Missing" if they are still under follow-up and do not have a result reported; if the "Missing" column only contains 0 values, it may be removed from the table. If all vital signs are "None" at the Pre-Vaccination 1 (Study Day 1) time point, that time point may be removed from the table. Unscheduled visits will only be considered in the "Max Severity Post Baseline" time point.]

Time Point	Treatment Group	N	None	Mild		Moderate		Severe		Missing
			n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
Pre-Vaccination 1 (Study Day 1)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 1 (Study Day 3)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 1 (Study Day 8)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 1 (Study Day 15)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Pre-Vaccination 2 (Study Day 29)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None	Mild		Moderate		Severe		Missing
			n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 2 (Study Day 31)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 2 (Study Day 36)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 2 (Study Day 43)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Pre-Vaccination 3 (Study Day 57)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
2 Days Post Vaccination 3 (Study Day 59)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
7 Days Post Vaccination 3 (Study Day 64)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None	Mild		Moderate		Severe		Missing
			n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	Low n (%)	High n (%)	n
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
14 Days Post Vaccination 3 (Study Day 71)[a]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
28 Days Post Vaccination 3 (Study Day 85)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
56 Days Post Vaccination 3 (Study Day 113)	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
Max Severity Post Baseline[b]	1 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	1 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	3 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x
	10 µg CJCV2+ALFQ	x	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x (xx)	x

Time Point	Treatment Group	N	None	Mild		Moderate		Severe		Missing
				Low	High	Low	High	Low	High	
			n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n

Notes: N = Number of participants in the Safety Population with a result at the specified time point.
Participants are counted once per time point.
[a] Cohort 1 was enrolled and completed follow-up under v4.0 of the protocol which required collection of vital signs at this time point which was not required beginning in v5.0 of the protocol.
[b] Indicates the maximum severity experienced by each participant at any time point post first vaccination, including unscheduled assessments.

Tables with similar format:

Table 92: Vital Signs by Time Point, Treatment Group, and Severity – Systolic Blood Pressure

Table 93: Vital Signs by Time Point, Treatment Group, and Severity – Diastolic Blood Pressure

Table 94: Vital Signs Summary Statistics by Time Point and Treatment Group – Temperature

[Implementation Note: Results are reported as XXX.X degrees Fahrenheit; report 2 decimal places for Mean, Standard Deviation, and Median and 1 decimal place for Min and Max. Only include the temperature measurements taken in-clinic and entered on the Vital Signs eCRF in this table (i.e., do not consider events from the participant's eMemory Aid).]

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Pre-Vaccination 1 (Study Day 1)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
2 Days Post Vaccination 1 (Study Day 3)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A
7 Days Post Vaccination 1 (Study Day 8)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
14 Days Post Vaccination 1 (Study Day 15)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
Pre-Vaccination 2 (Study Day 29)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
2 Days Post Vaccination 2 (Study Day 31)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A
7 Days Post Vaccination 2 (Study Day 36)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
14 Days Post Vaccination 2 (Study Day 43)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A
Pre-Vaccination 3 (Study Day 57)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
2 Days Post Vaccination 3 (Study Day 59)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A
7 Days Post Vaccination 3 (Study Day 64)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
14 Days Post Vaccination 3 (Study Day 71)[a]	n	x	x	N/A	N/A	N/A	N/A
	Mean	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Standard Deviation	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Median	xx.xx	xx.xx	N/A	N/A	N/A	N/A
	Min, Max	xx.x, xx.x	xx.x, xx.x	N/A	N/A	N/A	N/A
28 Days Post Vaccination 3 (Study Day 85)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
56 Days Post Vaccination 3 (Study Day 113)	n	x	x	x	x	x	x
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Time Point	Statistic	1 µg CJCV2 (N=X)	1 µg CJCV2+ALFQ (N=X)	3 µg CJCV2 (N=X)	3 µg CJCV2+ALFQ (N=X)	10 µg CJCV2 (N=X)	10 µg CJCV2+ALFQ (N=X)
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Notes: N = Number of participants in the Safety Population; n = Number of participants in the Safety Population with a result at the specified time point; N/A = Not Applicable.
Statistics other than n are reported as degrees Fahrenheit.
[a] Cohort 1 was enrolled and completed follow-up under v4.0 of the protocol which required collection of vital signs at this time point which was not required beginning in v5.0 of the protocol.

Tables with similar format:

Table 95: Vital Signs Summary Statistics by Time Point and Treatment Group – Pulse

[Implementation Note: Results are reported as XXX bpm; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max. Update the footnote with applicable units.]

Table 96: Vital Signs Summary Statistics by Time Point and Treatment Group – Systolic Blood Pressure

[Implementation Note: Results are reported as XXX mmHg; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max. Update the footnote with applicable units.]

Table 97: Vital Signs Summary Statistics by Time Point and Treatment Group – Diastolic Blood Pressure

[Implementation Note: Results are reported as XXX mmHg; report 1 decimal place for Mean, Standard Deviation, and Median and 0 decimal places for Min and Max. Update the footnote with applicable units.]

14.4 Summary of Concomitant Medications

Table 98: Number and Percentage of Participants with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group

[Implementation Note: Only include the "Any Level 2 Code" row if there is >1 distinct level 2 code. Only include Level 1 and Level 2 codes with a count > 0. Sort Level 1 code by descending frequency for All Participants ("Any Level 1 Code" should be first). Within Level 1 Code, sort the Level 2 codes by descending frequency for All Participants ("Any Level 2 Code" should be first). Any remaining ties will use alphabetical order.]

WHO Drug Code Level 1, Anatomical Group	WHO Drug Code Level 2, Therapeutic Subgroup	1 µg CJCV2 (N=X)		1 µg CJCV2+ALFQ (N=X)		3 µg CJCV2 (N=X)		3 µg CJCV2+ALFQ (N=X)		10 µg CJCV2 (N=X)		10 µg CJCV2+ALFQ (N=X)		All Participants (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any Level 1 Code	Any Level 2 Code	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[ATC Level 1 - 1]	Any Level 2 Code	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 3]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[ATC Level 1 – 2]	Any Level 2 Code	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[ATC 2 - 3]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Notes: N = Number of participants in the Safety Population.
Participants can only be counted once per Level 2 Code.

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Group Visual Characteristics for Figures

- Cohort/Vaccine Group
  - Different color for each of the 6 vaccine groups
  - Line pattern based on with or without adjuvant
  - Symbol shape based on Cohort; symbol fill based on with or without adjuvant

Group Label	Color	Line Pattern	Symbol
1 µg CJCV2	a	a	a, filled
1 µg CJCV2+ALFQ	b	b	a, unfilled
3 µg CJCV2	c	a	b, filled
3 µg CJCV2+ALFQ	d	b	b, unfilled
10 µg CJCV2	e	a	c, filled
10 µg CJCV2+ALFQ	f	b	c, unfilled

- Adjuvant Status Group

Group Label	Color	Line Pattern	Symbol
CJCV2	g	a	d, filled
CJCV2+ALFQ	h	b	d, unfilled

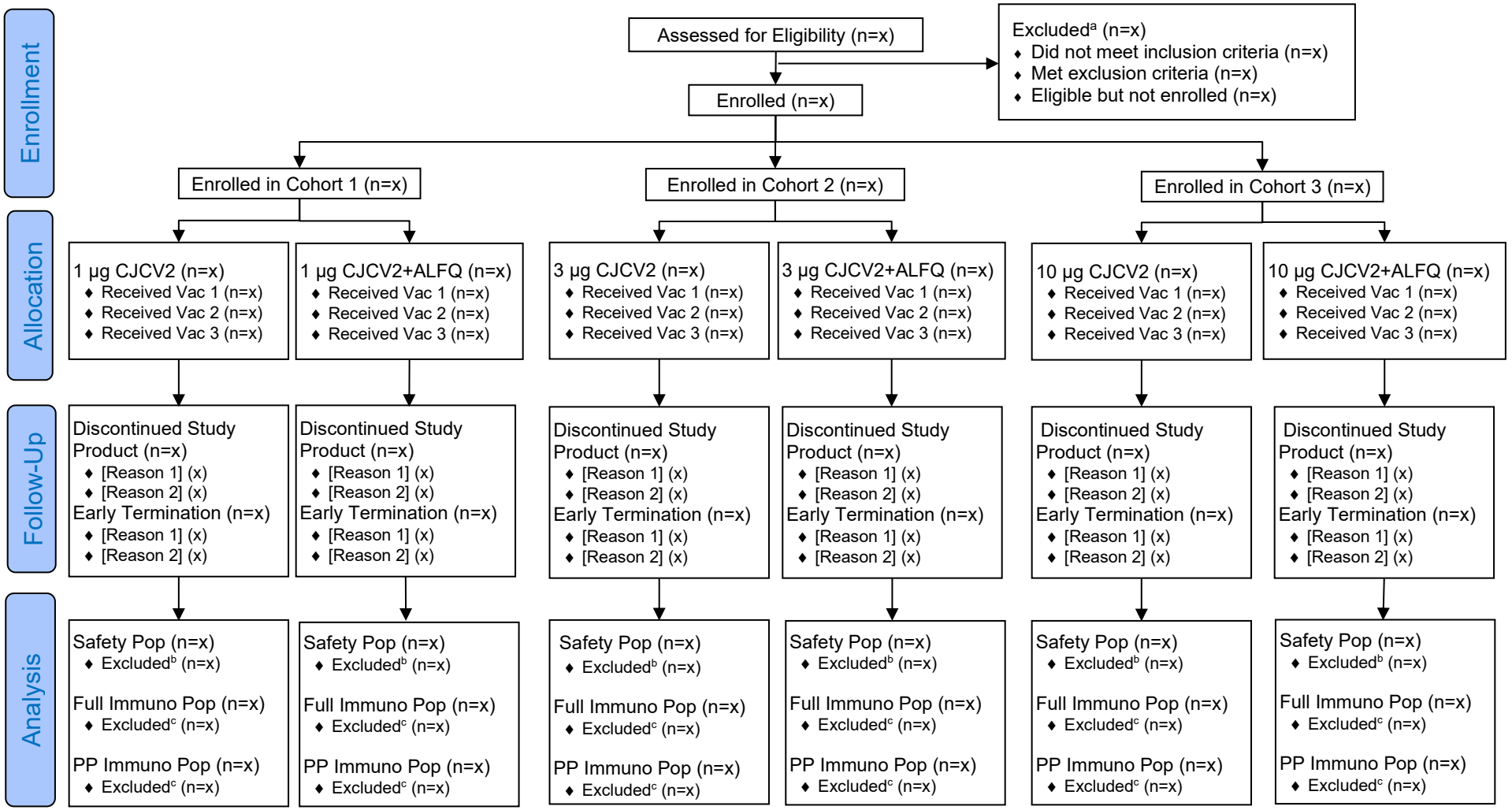
- Cohort Group

Group Label	Color	Line Pattern	Symbol
Cohort 1: 1 µg CJCV2	j	N/A	a, unfilled
Cohort 2: 3 µg CJCV2	k	N/A	b, unfilled
Cohort 3: 10 µg CJCV2	l	N/A	c, unfilled

The symbol will be unfilled to help visibility in the scatterplot.

10.1 Disposition of Participants

Figure 1: CONSORT Flow Diagram

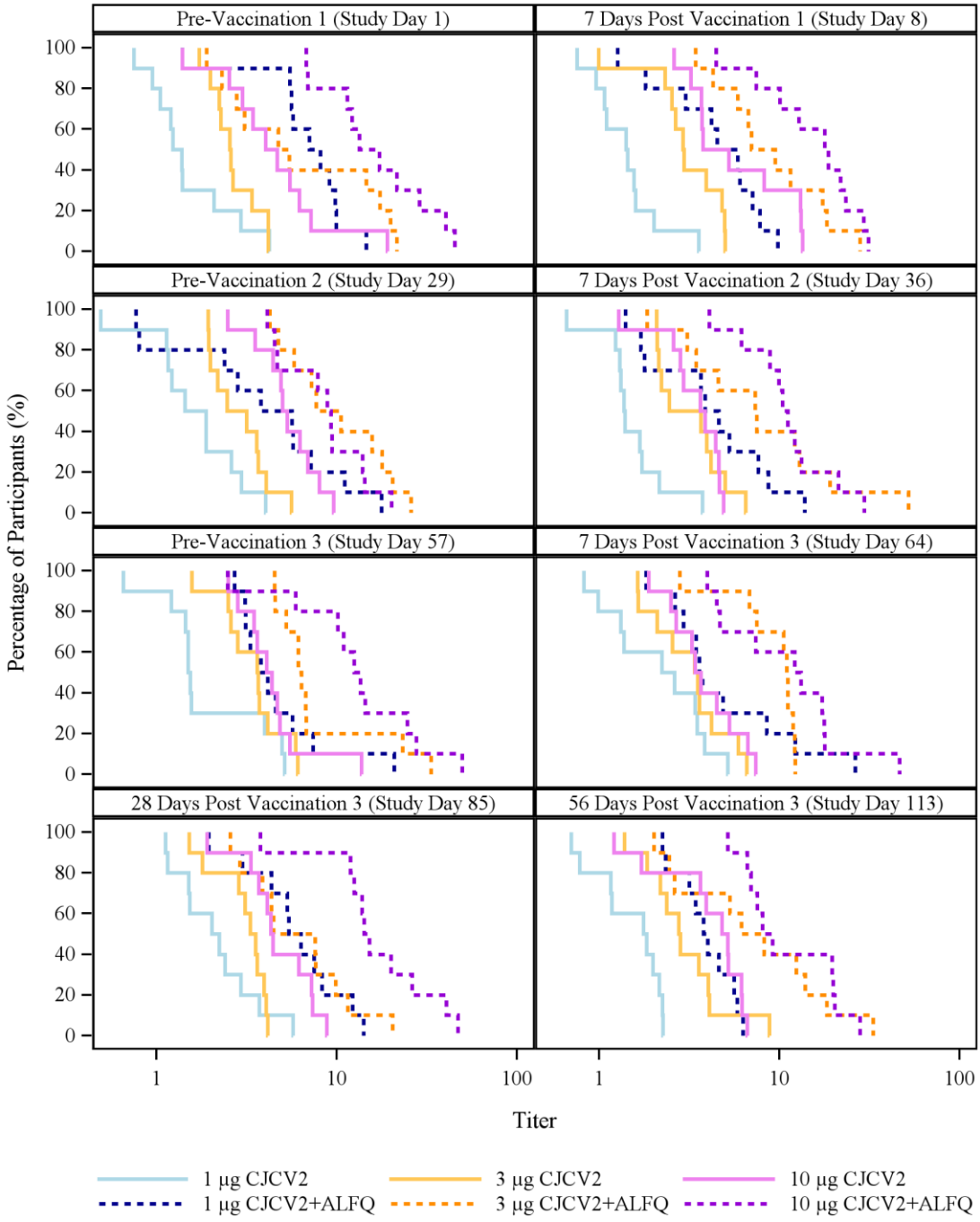


Notes: Vac = Vaccination; Immuno = Immunogenicity; Pop = Population.
[a] Reasons for screening failures are summarized in Section 14.1.1.
[b] Participants excluded because they did not receive any study vaccine.
[c] Details of analysis population exclusions are in Listing 16.2.3.

14.2.2 Immunogenicity Response Figures by Measure, Treatment Group, and Time Point

Figure 2: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgG Serum Antibodies by Time Point and Treatment Group, Full Immunogenicity Population

[Implementation note: The figure below is an example only. The figure will include 8 panels for Study Days 1, 8, 29, 36, 57, 64, 85, and 113; results will be grouped by analysis time point. If there is difficulty with the visibility of the figure, this figure may be split into separate figures as needed. The figure should use the Cohort/Vaccine Group attributes.]



Figures with similar format:

Figure 3: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgG Serum Antibodies by Time Point and Treatment Group, PP Immunogenicity Population

Figure 4: Reverse Cumulative Distribution of CRM_{197}-specific IgG Serum Antibodies by Time Point and Treatment Group, Full Immunogenicity Population

Figure 5: Reverse Cumulative Distribution of CRM_{197}-specific IgG Serum Antibodies by Time Point and Treatment Group, PP Immunogenicity Population

Figure 6: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgG ALS by Time Point and Treatment Group, Full Immunogenicity Population

[Implementation Note: This figure will have 4 panels for Study Days 1, 8, 36, and 64.]

Figure 7: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgG ALS by Time Point and Treatment Group, PP Immunogenicity Population

[Implementation Note: This figure will have 4 panels for Study Days 1, 8, 36, and 64.]

Figure 8: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgM Serum Antibodies by Time Point and Treatment Group, Full Immunogenicity Population

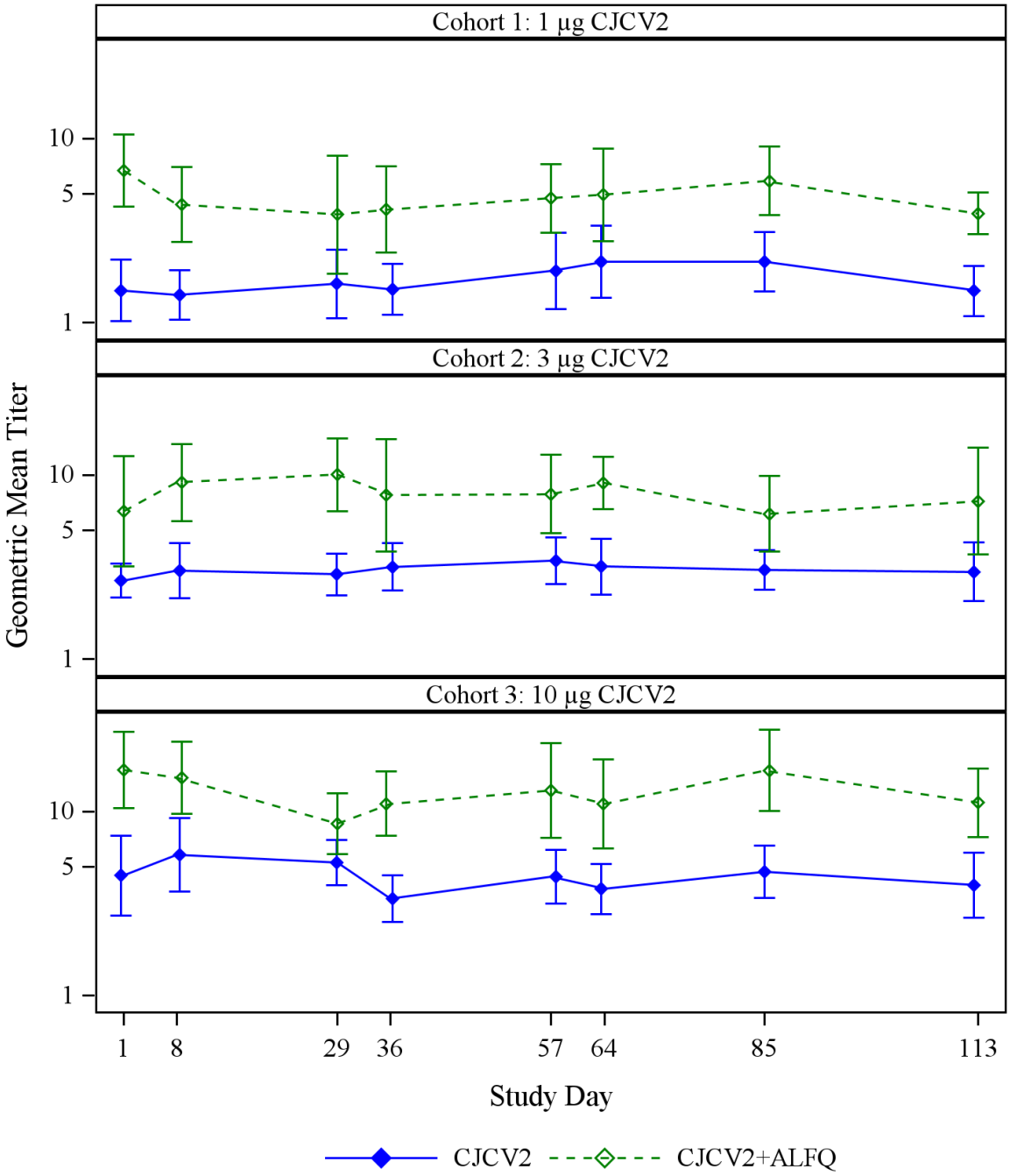
Figure 9: Reverse Cumulative Distribution of *C. jejuni* Capsule-specific IgM Serum Antibodies by Time Point and Treatment Group, PP Immunogenicity Population

Figure 10: Reverse Cumulative Distribution of CRM_{197}-specific IgM Serum Antibodies by Time Point and Treatment Group, Full Immunogenicity Population

Figure 11: Reverse Cumulative Distribution of CRM_{197}-specific IgM Serum Antibodies by Time Point and Treatment Group, PP Immunogenicity Population

Figure 12: Geometric Mean Time Trends of *C. jejuni* Capsule-specific IgG Serum Antibodies by Treatment Group, Full Immunogenicity Population

[Implementation note: The figure below is an example only. The figure will be paneled by cohort. Time points presented will be Study Days 1, 8, 29, 36, 57, 64, 85, and 113; results will be grouped by analysis time point. Include footnote, "Note: Error bars represent 95% confidence interval based on Student's t distribution.". The figure should use the Adjuvant Status Group attributes.]



Note: Error bars represent 95% confidence interval based on Student's t distribution.

Figures with similar format:

Figure 13: Geometric Mean Time Trends of *C. jejuni* Capsule-Specific IgG Serum Antibodies by Treatment Group, PP Immunogenicity Population

Figure 14: Geometric Mean Time Trends of CRM_{197}-specific IgG Serum Antibodies by Treatment Group, Full Immunogenicity Population

Figure 15: Geometric Mean Time Trends of CRM_{197}-specific IgG Serum Antibodies by Treatment Group, PP Immunogenicity Population

Figure 16: Geometric Mean Time Trends of *C. jejuni* Capsule-specific IgG ALS by Treatment Group, Full Immunogenicity Population

[Implementation Note: Time points presented will be Study Days 1, 8, 36, and 64.]

Figure 17: Geometric Mean Time Trends of *C. jejuni* Capsule-specific IgG ALS by Treatment Group, PP Immunogenicity Population

[Implementation Note: Time points presented will be Study Days 1, 8, 36, and 64.]

Figure 18: Geometric Mean Time Trends of *C. jejuni* Capsule-specific IgM Serum Antibodies by Treatment Group, Full Immunogenicity Population

Figure 19: Geometric Mean Time Trends of *C. jejuni* Capsule-specific IgM Serum Antibodies by Treatment Group, PP Immunogenicity Population

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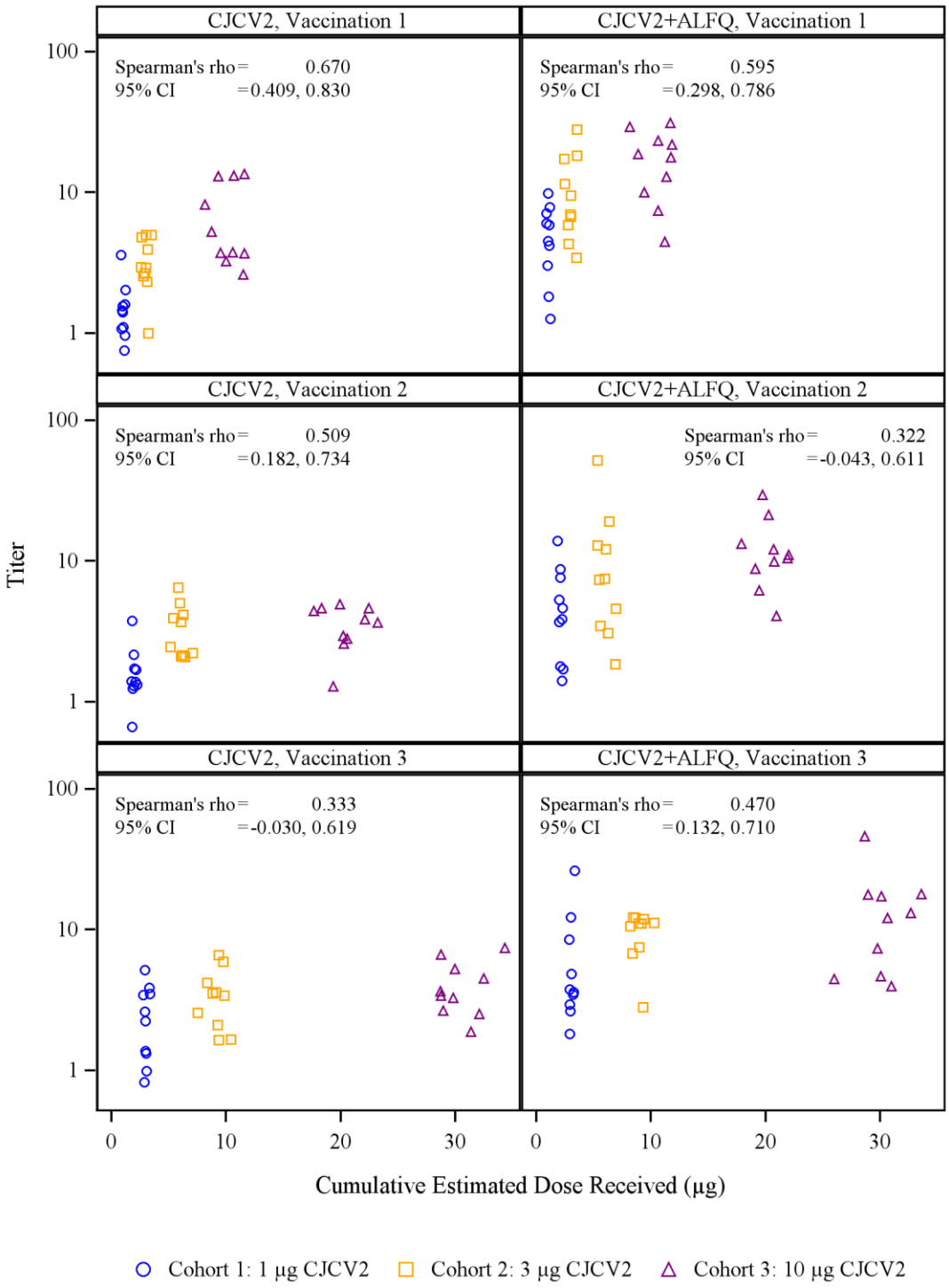
Figure 22: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and *C. jejuni* Capsule-specific IgG Serum Antibodies by ALFQ Status and Vaccination, Full Immunogenicity Population

[Implementation Note: The calculations for the correlations in these figures should match the calculations in the corresponding tables. The below is an example figure. The figure should use the Cohort Group attributes.]



Figures with similar format:

Figure 23: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and *C. jejuni* Capsule-specific IgG Serum Antibodies by ALFQ Status and Vaccination, PP Immunogenicity Population

Figure 24: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and CRM_{197}-specific IgG Serum Antibodies by ALFQ Status and Vaccination, Full Immunogenicity Population

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Figure 29: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and *C. jejuni* Capsule-specific IgM Serum Antibodies by ALFQ Status and Vaccination, PP Immunogenicity Population

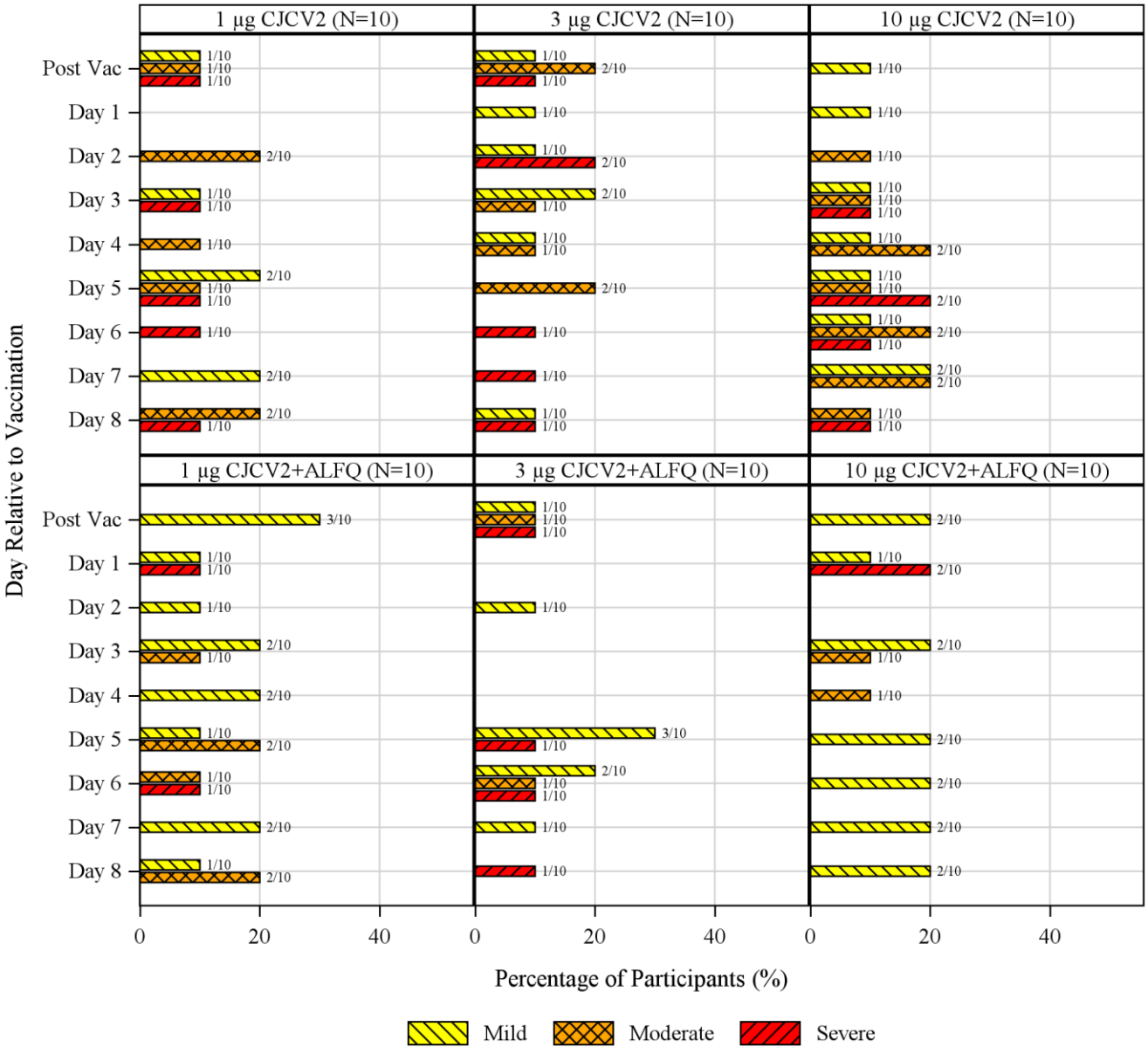
Figure 30: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and CRM_{197}-specific IgM Serum Antibodies by ALFQ Status and Vaccination, Full Immunogenicity Population

Figure 31: Scatterplot and Spearman's Correlation of Cumulative Estimated CJCV2 Dose and CRM_{197}-specific IgM Serum Antibodies by ALFQ Status and Vaccination, PP Immunogenicity Population

14.3.1.1 Solicited Adverse Events

Figure 32: Maximum Severity of Any Solicited Systemic Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 1

[Implementation note: The figure below is an example only. N is the number of participants in the Safety Population receiving specified vaccination. Post Vac is the in-clinic assessment 30 minutes after vaccination, and Day 1 is from the memory aid completed by the participant for the day of vaccination. Update footnotes with applicable vaccination number. If the figure is difficult to read, each figure in this section may be split into 3 separate figures by cohort.]



Notes: N = Number of participants in the Safety Population receiving Vaccination 1.
Post Vac is the in-clinic assessment 30 minutes after vaccination; Day 1 is from the memory aid completed by the participant for the day of vaccination.

Figures with similar format:

Figure 33: Maximum Severity of Any Solicited Systemic Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 2

Figure 34: Maximum Severity of Any Solicited Systemic Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 3

Figure 35: Maximum Severity of Any Solicited Systemic Symptom per Participant by Treatment Group and Day Relative to Vaccination, Any Vaccination

Figure 36: Maximum Severity of Any Solicited Local Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 1

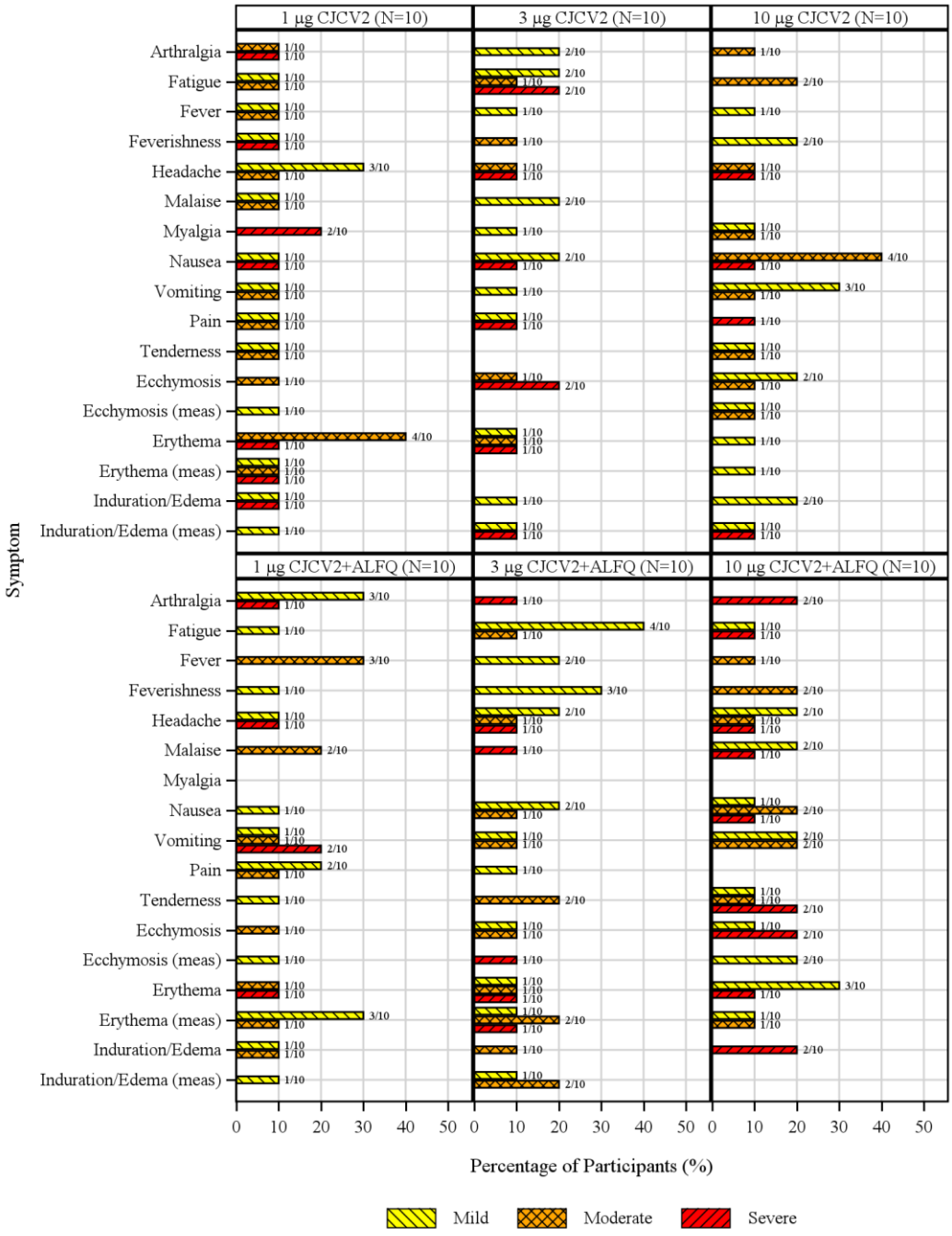
Figure 37: Maximum Severity of Any Solicited Local Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 2

Figure 38: Maximum Severity of Any Solicited Local Symptom per Participant by Treatment Group and Day Relative to Vaccination, Vaccination 3

Figure 39: Maximum Severity of Any Solicited Local Symptom per Participant by Treatment Group and Day Relative to Vaccination, Any Vaccination

Figure 40: Maximum Severity of Solicited Symptoms within 7 Days of Vaccination by Treatment Group and Symptom, Vaccination 1

[Implementation Note: The figure below is an example only. N will be the number of participants in the Safety Population receiving specified vaccination; update footnote to match the specified vaccination. The symptoms should be ordered with systemic symptoms first followed by local symptoms and sorted alphabetically within each category of symptoms. If the figure is difficult to read, each figure in this section may be split into 3 separate figures by cohort or into separate systemic and local figures.]



Notes: N = Number of participants in the Safety Population receiving Vaccination 1; meas = measurement.

Figures with similar format:

Figure 41: Maximum Severity of Solicited Symptoms within 7 Days of Vaccination by Treatment Group and Symptom, Vaccination 2

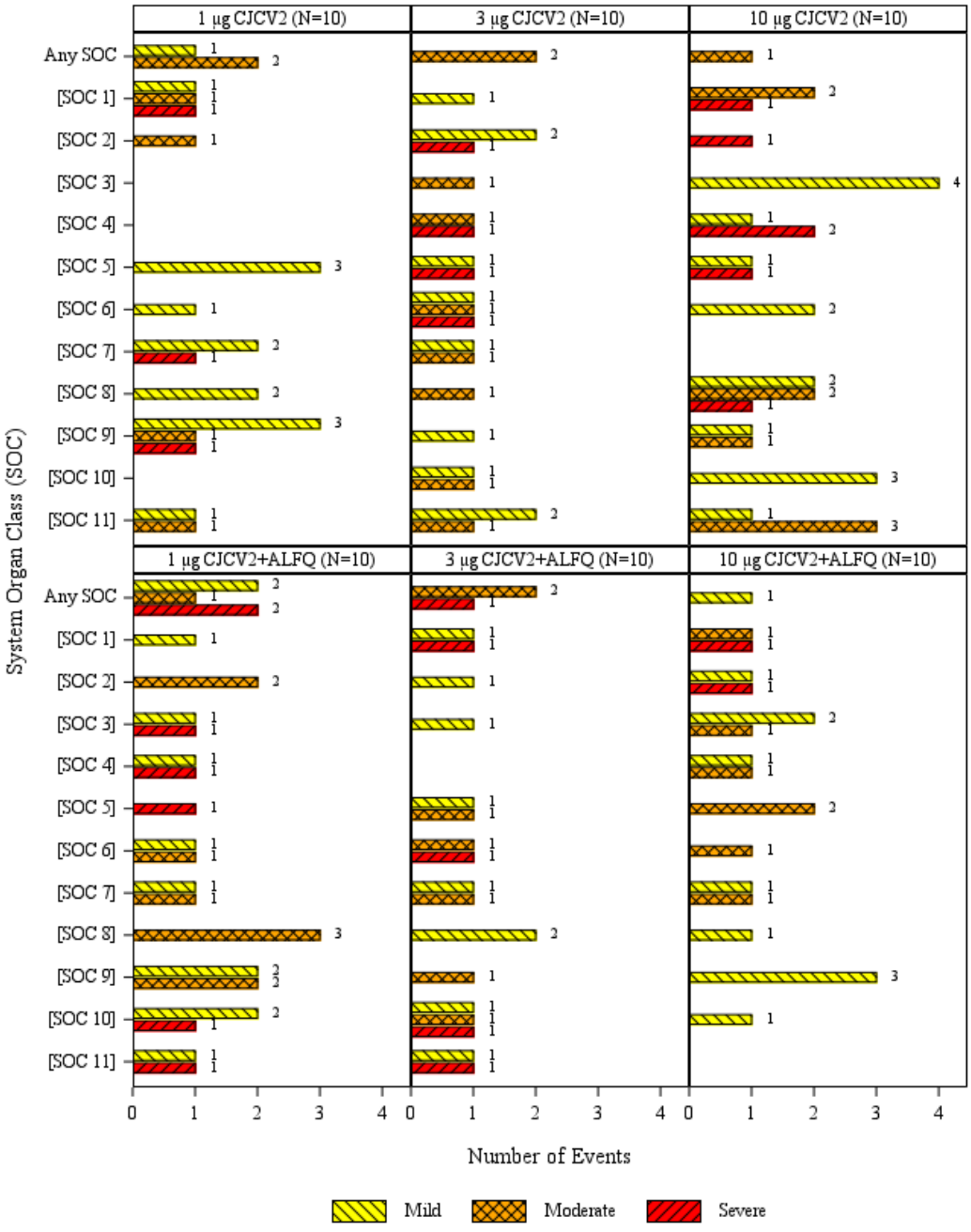
Figure 42: Maximum Severity of Solicited Symptoms within 7 Days of Vaccination by Treatment Group and Symptom, Vaccination 3

Figure 43: Maximum Severity of Solicited Symptoms within 7 Days of Vaccination by Treatment Group and Symptom, Any Vaccination

14.3.1.2 Unsolicited Adverse Events

Figure 44: Frequency of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Severity, Vaccination 1

[Implementation note: The figure below is an example only. Only include the SOCs with a count > 0. N is the number of participants in the Safety Population receiving the specified vaccination; update footnote to match the specified vaccination. If the figure is difficult to read, each figure in this section may be split into 3 separate figures by cohort. Sort the SOCs by descending frequency across all treatment groups ("Any SOC" should be first; any other ties should be in alphabetical order).]



Note: N = Number of participants in the Safety Population receiving Vaccination 1.

Figures with similar format:

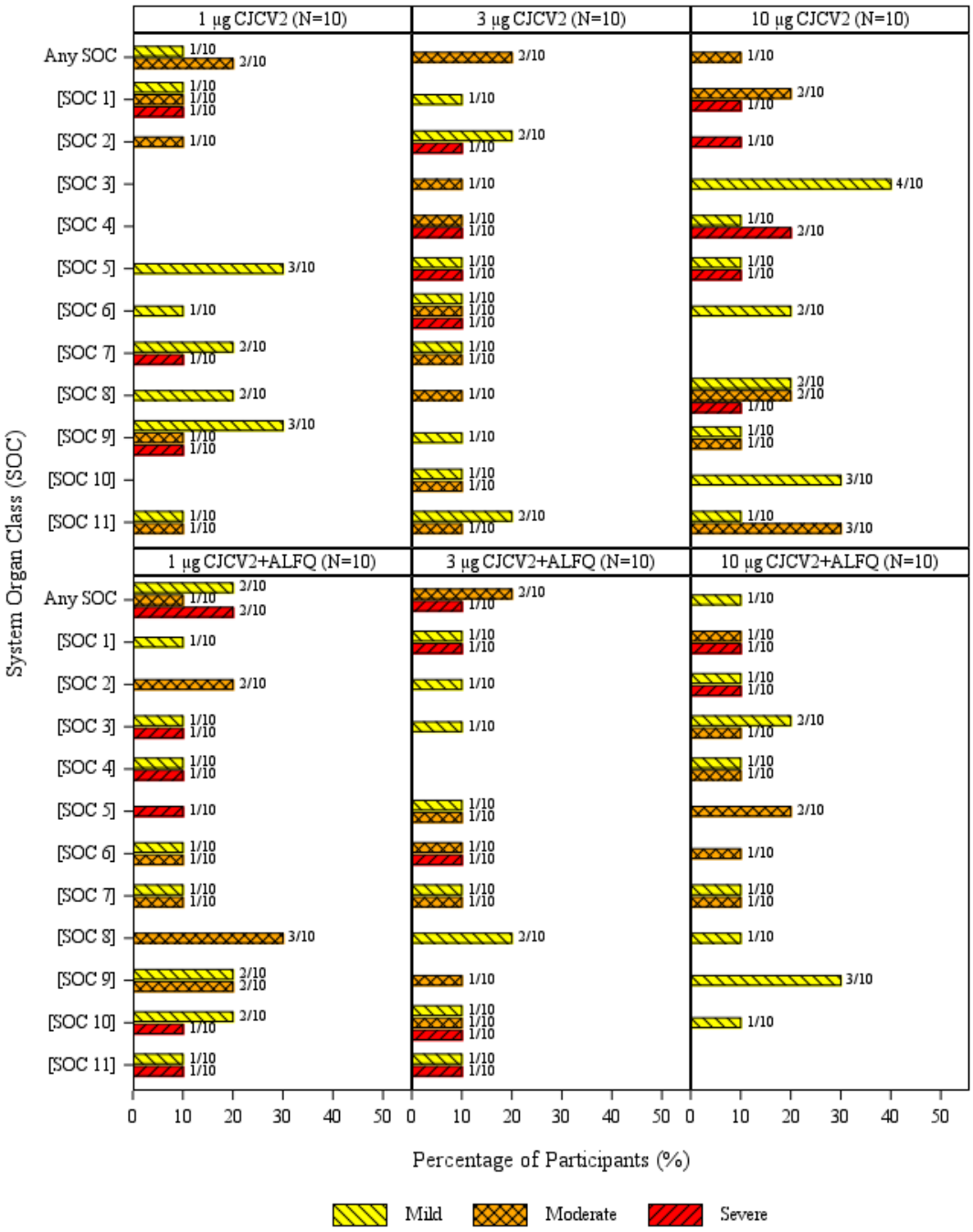
Figure 45: Frequency of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Severity, Vaccination 2

Figure 46: Frequency of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Severity, Vaccination 3

Figure 47: Frequency of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Severity, Any Vaccination

Figure 48: Incidence of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Maximum Severity, Vaccination 1

[Implementation note: The figure below is an example only. Only include SOCs with a count > 0. N is the number of participants in the Safety Population receiving specified vaccination; update footnote to match the specified vaccination. If the figure is difficult to read, each figure in this section may be split into 3 separate figures by cohort. Sort the SOCs by descending frequency of incidence across all treatment groups ("Any SOC" should be first; any other ties should be in alphabetical order).]



Note: N = Number of participants in the Safety Population receiving Vaccination 1.

Figures with similar format:

Figure 49: Incidence of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Maximum Severity, Vaccination 2

Figure 50: Incidence of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Maximum Severity, Vaccination 3

Figure 51: Incidence of Related Unsolicited Adverse Events by Treatment Group, MedDRA System Organ Class, and Maximum Severity, Any Vaccination

APPENDIX 3. LISTINGS MOCK-UPS

LISTINGS

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Listing 1: **Listing of Participants Receiving Investigational Product**

[Implementation Note: The timing of vaccinations will be the study day relative to the first vaccination where Study Day 1 will be the day of the first vaccination. Sort by Treatment Group, Participant ID, and Vaccination Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Vaccination Number	Study Day of Vaccination	Actual Study Product Received	Estimated CJCV2 Dose Received (µg)	Cumulative Estimated CJCV2 Dose Received (µg)
1 µg CJCV2	EHD.XXXXX	Vac 1	X	CJCV2	X.XX	X.XX
1 µg CJCV2+ALFQ		Vac 2		CJCV2+ALFQ		
3 µg CJCV2		Vac 3				
3 µg CJCV2+ALFQ						
10 µg CJCV2						
10 µg CJCV2+ALFQ						

Notes: Vac = Vaccination.
Dose verification results are estimated for each batch prepared; all participants vaccinated with the same batch have the same estimated CJCV2 dose received.

16.2 Database Listings by Participant

16.2.1 Discontinued Participants

Listing 2: Early Terminations or Discontinued Participants

[Implementation Note: The "Category" will either be "Early Termination" or "Study Product Discontinuation". In the "Reason" column, include the reason and any applicable "specify" fields from the Study Status or Discontinuation of Treatment eCRF. The "Study Day" column will be the study day relative to the first vaccination where Study Day 1 will be the day of the first vaccination, and Study Day -1 will be the day prior to the first vaccination. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and Category. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Category	Reason for Early Termination or Study Product Discontinuation	Study Day
1 µg CJCV2	EHD.XXXXX	Study Product Discontinuation	[reason]	X
1 µg CJCV2+ALFQ		Early Termination		
3 µg CJCV2				
3 µg CJCV2+ALFQ				
10 µg CJCV2				
10 µg CJCV2+ALFQ				

16.2.2 Protocol Deviations

Listing 3: Participant-Specific Protocol Deviations

[Implementation Note: In the "Deviation" column, include the deviation and all applicable "specify" fields from the Protocol Deviation eCRF. If "Reason for Deviation" is "Other", concatenate the "specify" field separated by a colon, e.g., "Other: [Reason entered by site]". The "Study Day" column will be the study day relative to the first vaccination where Study Day 1 is the day of the first vaccination, and Study Day -1 is the day prior to the first vaccination. For the "Deviation Resulted in AE?" column, if the deviation resulted in an unsolicited AE, display "Yes, Unsolicited" followed by the AE number in parentheses, e.g., "Yes, Unsolicited (003)". If the deviation resulted in a solicited AE, display "Yes, Solicited" followed by the symptom in parentheses, e.g., "Yes, Solicited (Nausea)". If there are no comments, display "None" in the "Comments" column. If there are no comments for any deviations, the "Comments" column may be removed. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. The footnotes should only include abbreviations appearing in the listing. Sort by Treatment Group, Participant ID, and DV Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	DV Number	Deviation	Deviation Category	Deviation Class[a]	Study Day	Reason for Deviation	Deviation Resulted in AE?	Deviation Resulted in Participant Termination?	Deviation Affected Product Stability?	Deviation Resolution	Comments
1 µg CJCV2	EHD.XXXXX	XXX			Major	X		No	No	No		
1 µg CJCV2+ALFQ					Minor			Yes, Unsolicited (XXX)	Yes	Yes		
3 µg CJCV2								Yes, Solicited ([symptom])		N/A		
3 µg CJCV2+ALFQ												
10 µg CJCV2												
10 µg CJCV2+ALFQ												

Notes: DV = Deviation; AE = Adverse Event; N/A = Not Applicable.
[a] A deviation is classified as major if it has the potential to negatively impact the rights, welfare, or safety of the participant or to substantially negatively impact the scientific integrity or validity of the study.

Listing 4: Non-Participant-Specific Protocol Deviations

[Implementation Note: In the "Deviation" column, include the deviation and all applicable "specify" fields from the Non-Subject Specific Protocol Deviation eCRF. If "Reason for Deviation" is "Other", concatenate "specify" field separated by a colon, e.g., "Other: [Reason entered by site]". If there are no comments, display "None" in the "Comments" column. If there are no comments for any deviations, the "Comments" column may be removed. Only include the N/A footnote if there is an N/A value in the listing. Sort by Deviation Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Deviation Number	Start Date	End Date	Deviation	Deviation Category	Deviation Class[a]	Reason for Deviation	Deviation Resulted in Participant Termination?	Deviation Affected Product Stability?	Deviation Resolution	Comments
XXX	DDMMMYYYY	DDMMMYYYY			Major		No	No		
					Minor		Yes	Yes		
								N/A		

Notes: Class = Classification; N/A = Not Applicable.
[a] A deviation is classified as major if it has the potential to negatively impact the rights, welfare, or safety of the participant or to substantially negatively impact the scientific integrity or validity of the study.

16.2.3 Participants Excluded from Analysis

Listing 5: Participants Excluded from Analysis Populations

[Implementation Note: The "Included in Safety Population?" and "Included in Full Immunogenicity Population?" columns should either display "Yes" or "No: [reason for exclusion]". The "Included in PP Immunogenicity Population?" column should either display "Yes: All visits included", "Yes: Visit(s) [XX] excluded: [reason for exclusion of visits]", or "No: [reason for exclusion of participant]". The "Visits(s) [XX] excluded: [reason for exclusion of visits]" may be repeated and separated by a semicolon if there are groups of visits with different reasons for exclusion. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group and Participant ID. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Included in Safety Population?[a]	Included in Full Immunogenicity Population?[b]	Included in PP Immunogenicity Population?[c]
1 µg CJCV2	EHD.XXXXX	Yes	Yes	No: [reason for exclusion]
1 µg CJCV2+ALFQ		No	No	Yes: All visits included
3 µg CJCV2				Yes: Visit(s) [XX] excluded: [reason]; Visit(s) [XX] excluded: [reason]
3 µg CJCV2+ALFQ				
10 µg CJCV2				
10 µg CJCV2+ALFQ				

[a] Participants are excluded from the Safety Population if they did not receive any study vaccine.
[b] Participants are excluded from the Full Immunogenicity Population if they did not contribute both pre- and at least one post-study vaccination blood sample.
[c] Details on inclusion or exclusion of specific assay results are included in Section 16.2.6.

16.2.4 Demographic Data

Listing 6: Demographic and Baseline Characteristics

[Implementation Note: If a participant is multi-racial, the "Race" column should be formatted as "Multiple: [list races separated by a comma]". In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group and Participant ID. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Sex	Age at Enrollment (years)	Ethnicity	Race	Height (cm)	Weight (kg)	BMI (kg/m^2)
1 µg CJCV2	EHD.XXXXX	Male	XX	Hispanic or Latino	American Indian or Alaskan Native	xxx.x	xx.x	xx.x
1 µg CJCV2+ALFQ		Female		Not Hispanic or Latino	Asian			
3 µg CJCV2				Unknown	Native Hawaiian or other Pacific Islander			
3 µg CJCV2+ALFQ				Not Reported	Black or African American			
10 µg CJCV2					White			
10 µg CJCV2+ALFQ					Multiple: [Race 1, Race 2, …]			
					Unknown			
Note: BMI = Body Mass Index; cm = Centimeters; kg = Kilograms; m = Meters.								

Listing 7: Pre-Existing and Concurrent Medical Conditions

[Implementation Note: "Condition Start" and "Condition End" are relative to the first vaccination where the day of the first vaccination is Study Day 1, and the day prior to first vaccination is Study Day -1. Categorize the start/end as follows: >5 years prior to enrollment, 1-5 years prior to enrollment, 1-12 months prior to enrollment, within 1 month of enrollment, or during study. If the condition is ongoing, display "Ongoing" in the "Condition End Day" column. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and MH Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	MH Number	Medical History Term	Condition Start[a]	Condition End[a]	MedDRA System Organ Class	MedDRA Preferred Term
1 µg CJCV2	EHD.XXXXX	XXX		> 5 years prior	> 5 years prior		
1 µg CJCV2+ALFQ				1-5 years prior	1-5 years prior		
3 µg CJCV2				1-12 months prior	1-12 months prior		
3 µg CJCV2+ALFQ				< 1 month prior	< 1 month prior		
10 µg CJCV2				During study	Ongoing		
10 µg CJCV2+ALFQ							

Notes: MH = Medical History; MedDRA = Medical Dictionary for Regulatory Activities.
[a] Relative to study enrollment.

16.2.6 Individual Immunogenicity Response Data

Listing 8: Individual Immunogenicity Response Data

[Implementation Note: The "Result (Log_{10} Titer)" column will show the results as reported by the lab; results below the limit of quantification will display "< LLOQ" where LLOQ will be replaced by the actual LLOQ for the assay. The "Result (Titer)" column will show the Log_{10} Titer result converted to Titer as specified in Section 4.5.2; results <LLOQ will be imputed as specified in Section 6.5. The "Actual Study Day" column will be the day relative to first vaccination where Study Day 1 is the day of first vaccination and Study Day -1 is the day prior to first vaccination. The "Analysis Time Point" column should use the same labels as the summary tables. The columns to indicate whether each value was included in the analysis will be "Yes" if the value is included, "Yes – Imputed Value" if the value was imputed because it was <LLOQ, or "No[x]" where [x] will be a footnote indicating the reason for exclusion. If the reason for exclusion is because the participant was excluded from the analysis population, only that reason needs to be included; otherwise, include all applicable reasons separated by commas. The footnotes are example reasons for exclusion; only include the reasons observed in the study. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, Actual Study Day, and Assay. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Assay	Result (Log_{10} Titer)	Result (Titer)	Included in Full Immunogenicity Population?	Included in PP Immunogenicity Population?
1 µg CJCV2	EHD.XXXXX	Pre-Vaccination 1 (Study Day 1)	X	*C. jejuni* Capsule-specific IgG Serum Antibody	X.XX	XX	Yes	Yes
1 µg CJCV2+ALFQ		7 Days Post Vaccination 1 (Study Day 8)		CRM_{197}-specific IgG Serum Antibody	< [LLOQ]		Yes – Imputed Value	Yes – Imputed Value
3 µg CJCV2		Pre-Vaccination 1 (Study Day 29)		*C. jejuni* Capsule-specific IgG ALS			No[x]	No[x]
3 µg CJCV2+ALFQ		7 Days Post Vaccination 2 (Study Day 36)		*C. jejuni* Capsule-specific IgM Serum Antibody				
10 µg CJCV2		Pre-Vaccination 3 (Study Day 57)		CRM_{197}-specific IgM Serum Antibody				
10 µg CJCV2+ALFQ		7 Days Post Vaccination 3 (Study Day 64)						

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Assay	Result (Log_{10} Titer)	Result (Titer)	Included in Full Immunogenicity Population?	Included in PP Immunogenicity Population?
		28 Days Post Vaccination 3 (Study Day 85)						
		56 Days Post Vaccination 3 (Study Day 113)						

Notes: PP = Per Protocol.
Results <LLOQ are imputed as the LOD for the assay.
[a] Participant is excluded from analysis population because they did not contribute both pre- and at least one post-study vaccination blood sample.
[b] Participant is excluded from analysis population because they did not meet eligibility criteria at baseline.
[c] Visit occurred after a major protocol deviation.
[d] Visit occurred out of window.
[e] [Reason for exclusion].

16.2.7 Adverse Events

Listing 9: Solicited Events – Systemic Symptoms

[Implementation Note: In the "Vaccination Number (Study Day)" column, display the vaccination number followed by the actual study day the vaccination was received in parentheses, e.g., "Vac 1 (Day 1)". The "Severity" column for Fever should include the measurement in parentheses after the result, e.g., "Mild (100.7° F)". Include both pre- and post-vaccination assessments. For the "Day Relative to Vaccination" column, the day should be relative to the specified vaccination number; "Pre-Vac" is the pre-vaccination assessment, "Post Vac" is the in-clinic assessment 30 minutes after vaccination, and Day 1 is from the memory aid completed by the participant for the day of vaccination. For events ongoing past Day 8, the "Vaccination Number (Study Day)" and "Day Relative to Vaccination" columns should include the days of start (beyond Day 8 post-vaccination) and end, e.g., (Day 9 – Day 12); the "Severity" column will be the maximum severity (and measurement if applicable) during that time period. Include all solicited events from the Treatment Administration Record and Solicited Events eCRFs and temperatures collected on the Vital Signs eCRF within 7 days of each vaccination. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, Vaccination Number, Day Relative to Vaccination, and Symptom. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Vaccination Number (Study Day)	Day Relative to Vaccination	Assessment[a]	Symptom	Severity	Attributed to Alternate Etiology?[b]
1 µg CJCV2	EHD.XXXXX	Vac 1 (Day 1)	Pre-Vac	MA	Arthralgia	None	Yes: [alternate etiology]
1 µg CJCV2+ALFQ		Vac 1 (Day 1)	Post Vac	Clinic	Fatigue	Mild	No
3 µg CJCV2		Vac 1 (Day 1)	Day 1		Fever	Moderate	N/A
3 µg CJCV2+ALFQ		Vac 1 (Day 2)	Day 2		Feverishness	Severe	
10 µg CJCV2		Vac 1 (Day 3)	Day 3		Headache	[Severity] (XXX.X° F)	
10 µg CJCV2+ALFQ		Vac 1 (Day 4)	Day 4		Malaise		
		Vac 1 (Day 5)	Day 5		Myalgia		
		Vac 1 (Day 6)	Day 6		Nausea		
		Vac 1 (Day 7)	Day 7		Vomiting		
		Vac 1 (Day 8)	Day 8				
		Vac 1 (Day 9 – Day X)	Day 9 – Day X				
		Vac 2 (Day 29)	Pre-Vac				
		Vac 2 (Day 29)	Post Vac				

Treatment Group	Participant ID	Vaccination Number (Study Day)	Day Relative to Vaccination	Assessment[a]	Symptom	Severity	Attributed to Alternate Etiology?[b]
		Vac 2 (Day 29)	Day 1				
		Vac 2 (Day 30)	Day 2				
		Vac 2 (Day 31)	Day 3				
		Vac 2 (Day 32)	Day 4				
		…	…				
		Vac 2 (Day 37 – Day Y)	Day 9 – Day X				
		…	…				

Note: "Pre-Vac" is the pre-vaccination assessment, "Post Vac" is the in-clinic assessment 30 minutes after vaccination, and "Day 1" is from the memory aid completed by the participant for the day of vaccination.
[a] MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF. Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.).
[b] Severe (Grade 3) events only.

Listing 10: Solicited Events – Local Symptoms

[Implementation Note: In the "Vaccination Number (Study Day)" column, display the vaccination number followed by the actual study day the vaccination was received in parentheses, e.g., "Vac 1 (Day 1)". The "Severity" column for quantitative measurements should include the measurement in parentheses after the result, e.g., "Mild (3 mm)". For the "Day Relative to Vaccination" column, "Post Vac" is the assessment 30 minutes after vaccination, and "Day 1" is the maximum over the remainder of the day of vaccination. The "Day Relative to Vaccination Symptom Resolved" column will be relative to the associated vaccination where the day of the associated vaccination is Day 1. For events ongoing past Day 8, the "Vaccination Number (Study Day)" and "Day Relative to Vaccination" columns should include the days of start (Day 9) and end, e.g., (Day 9 – Day 12); the "Severity" column will be the maximum severity (and measurement if applicable) during that time period. Include all solicited events from the Treatment Administration Record and Solicited Events eCRFs. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, Vaccination Number, Day Relative to Vaccination, and Symptom. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Vaccination Number (Study Day)	Day Relative to Vaccination	Assessment[a]	Symptom	Severity
1 µg CJCV2	EHD.XXXXX	Vac 1 (Day 1)	Post Vac	MA	Ecchymosis	None
1 µg CJCV2+ALFQ		Vac 1 (Day 1)	Day 1	Clinic	Ecchymosis (measurement)	Mild
3 µg CJCV2		Vac 1 (Day 2)	Day 2		Erythema	Moderate
3 µg CJCV2+ALFQ		Vac 1 (Day 3)	Day 3		Erythema (measurement)	Severe
10 µg CJCV2		Vac 1 (Day 4)	Day 4		Induration/Edema	None (0 mm)
10 µg CJCV2+ALFQ		Vac 1 (Day 5)	Day 5		Induration/Edema (measurement)	Mild (X mm)
		Vac 1 (Day 6)	Day 6		Pain	Moderate (X mm)
		Vac 1 (Day 7)	Day 7		Tenderness	Severe (X mm)
		Vac 1 (Day 8)	Day 8			
		Vac 1 (Day 9 – Day X)	Day 9 – Day X			
		Vac 2 (Day 29)	Post Vac			
		Vac 2 (Day 29)	Day 1			
		Vac 2 (Day 30)	Day 2			
		Vac 2 (Day 31)	Day 3			

Treatment Group	Participant ID	Vaccination Number (Study Day)	Day Relative to Vaccination	Assessment[a]	Symptom	Severity
		Vac 2 (Day 32)	Day 4			
		…	…			
		Vac 2 (Day 37 – Day Y)	Day 9 – Day X			
		…	…			

Note: "Post Vac" is the in-clinic assessment 30 minutes after vaccination, and "Day 1" is from the memory aid completed by the participant for the day of vaccination.
[a] MA = Data reported by participant on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF. Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.).

Listing 11: Unsolicited Adverse Events

[Implementation Note: The "No. of Days Post Associated Vac (Duration)" column will be the day of AE onset with the day of associated vaccination being Day 1; the duration will be the duration of the AE in days. The "SAE/NOCMC/MAAE/PIMMC/SUSAR?" will be "No" if the AE does not qualify as any of those events; if the AE does qualify as one of those events, the cell value should be "Yes: XXX" with the applicable event (or comma separated list of applicable events if more than 1) replacing "XXX". In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. The footnotes should only include abbreviations appearing in the listing. Sort by Treatment Group, Participant ID, and AE Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Adverse Event	Associated with Vac No.	No. of Days Post Associated Vac (Duration)	Severity	SAE/ NOCMC/ MAAE/ PIMMC/ SUSAR?	Relationship to Study Vaccination (If Not Related, Alternate Etiology)	Action Taken with Study Vaccinations	Participant Discontinued Due to AE?	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX										
	Vac [X]	Day X (Y days)	[Mild, Moderate, Severe]	[No, Yes: XXX]	[Related, Not Related ([alternate etiology])]		[Yes, No]			
Comments:										
Treatment Group: [X] µg [CJCV2 or CJCV2+ALFQ], Participant ID: EHD.XXXXX, AE Number: XXX										
Comments:										
Notes: Vac = Vaccination; No. = Number; SAE = Serious Adverse Event; NOCMC = New Onset Chronic Medical Condition; MAAE = Medically Attended Adverse Event; PIMMC = Potentially Immune-Mediated Medical Condition; SUSAR = Suspected Unexpected Serious Adverse Reaction; AE = Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities; N/A = Not Applicable. For additional details about SAEs, see Section 14.3.2.										

16.2.8 Individual Laboratory Measurements

Listing 12: Clinical Laboratory Results – Chemistry

[Implementation Note: Actual study day will be the day relative to first vaccination where Study Day 1 is the day of first vaccination, and Study Day -1 is the day prior to first vaccination. The "Analysis Time Point" column should use the same labels as the summary tables. For all results, indicate the severity grading in parentheses after the numeric result, e.g., "X.X (Mild)". In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. The footnotes should only contain abbreviations appearing in the listing. Sort by Treatment Group, Participant ID, Actual Study Day, and Laboratory Parameter. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Sex	Laboratory Parameter (Units)	Result (Severity Grade)	Reference Range Low	Reference Range High
1 µg CJCV2	EHD.XXXXX	Screening (Study Day -30 to -2)	X	Male	ALT (U/L)	X (None)	XXX	XXX
1 µg CJCV2+ALFQ		7 Days Post Vaccination 1 (Study Day 8)		Female	Creatinine (mg/dL)	X (ONR)	X.XX	X.XX
3 µg CJCV2		7 Days Post Vaccination 2 (Study Day 36)			Potassium (mEq/L)	X (Mild)	X.X	X.X
3 µg CJCV2+ALFQ		7 Days Post Vaccination 3 (Study Day 64)			Sodium (mEq/L)	X (Moderate)	XXX	XXX
10 µg CJCV2		Unscheduled Visit			Total Bilirubin (mg/dL)	X (Severe)	X.X	X.X
10 µg CJCV2+ALFQ								
Note: ALT = Alanine Aminotransferase; ONR = Outside Normal Range; U = Units; L = Liter; dL = deciliter; mg = milligram; mEq = milliequivalent.								

Listing 13: Clinical Laboratory Results – Hematology

[Implementation Note: "Actual Study Day" will be the day relative to first vaccination where Study Day 1 is the day of first vaccination, and Study Day -1 is the day prior to the day of first vaccination. The "Analysis Time Point" column should use the same labels as the summary tables. For all results, indicate the severity grading in parentheses after the numeric result, e.g., "X.X (Mild)". In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. The footnotes should only contain abbreviations appearing in the listing. Sort by Treatment Group, Participant ID, Actual Study Day, and Laboratory Parameter. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Sex	Laboratory Parameter (Units)	Result (Severity Grade)	Reference Range Low	Reference Range High
1 µg CJCV2	EHD.XXXXX	Screening (Study Day -30 to -2)	X	Male	ANC (x 10^3/µL)	X (None)	X	X
1 µg CJCV2+ALFQ		7 Days Post Vaccination 1 (Study Day 8)		Female	Hemoglobin (g/dL)	X (ONR)		
3 µg CJCV2		7 Days Post Vaccination 2 (Study Day 36)			Platelets (x 10^3/µL)	X (Mild)		
3 µg CJCV2+ALFQ		7 Days Post Vaccination 3 (Study Day 64)			WBC (x 10^3/µL)	X (Moderate)		
10 µg CJCV2		Unscheduled Visit				X (Severe)		
10 µg CJCV2+ALFQ								

Note: ANC = Absolute Neutrophil Count; WBC = White Blood Cells; ONR = Outside Normal Range; g = grams; dL = Deciliter; µL = microliter.

16.2.9 Vital Signs and Physical Exam Findings

Listing 14: Vital Signs

[Implementation Note: Include all vital sign assessments reported on the Vital Signs eCRF including scheduled and unscheduled visits. The "Actual Study Day" column will be relative to the day of first vaccination where Study Day 1 is the day of first vaccination, and Study Day -1 is the day prior to first vaccination. The "Analysis Time Point" column should use the same labels as the summary tables. For all results, indicate the severity grading in parentheses after the numeric result, e.g., "X.X (Mild)". In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and Actual Study Day. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Temperature (°F)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (bpm)
1 µg CJCV2	EHD.XXXXX	Screening (Study Day -30 to -2)	X	XXX.X (None)	XXX (None)	XXX (None)	XXX (None)
1 µg CJCV2+ALFQ		Pre-Vaccination 1 (Study Day 1)		XXX.X (Mild)	XXX (Mild)	XXX (Mild)	XXX (Mild)
3 µg CJCV2		2 Days Post Vaccination 1 (Study Day 3)		XXX.X (Moderate)	XXX (Moderate)	XXX (Moderate)	XXX (Moderate)
3 µg CJCV2+ALFQ		7 Days Post Vaccination 1 (Study Day 8)		XXX.X (Severe)	XXX (Severe)	XXX (Severe)	XXX (Severe)
10 µg CJCV2		14 Days Post Vaccination 1 (Study Day 15)					
10 µg CJCV2+ALFQ		Pre-Vaccination 2 (Study Day 29)					
		2 Days Post Vaccination 2 (Study Day 31)					
		7 Days Post Vaccination 2 (Study Day 36)					
		14 Days Post Vaccination 2 (Study Day 43)					
		Pre-Vaccination 3 (Study Day 57)					
		2 Days Post Vaccination 3 (Study Day 59)					
		7 Days Post Vaccination 3 (Study Day 64)					
		14 Days Post Vaccination 3 (Study Day 71)					
		28 Days Post Vaccination 3 (Study Day 85)					
		56 Days Post Vaccination 3 (Study Day 113)					
		Unscheduled Visit					

Notes: °F = Degrees Fahrenheit; mmHg = millimeters of mercury; bpm = beats per minute.

Listing 15: Physical Exam Findings

[Implementation Note: The "Actual Study Day" will be the day relative to first vaccination where Study Day 1 is the day of first vaccination, and Study Day -1 is the day prior to first vaccination. The "Analysis Time Point" column should be based on the study visit; see example labels in listing below. For the "Reported as an AE?" column, if the finding was reported as an unsolicited AE, display "Yes, Unsolicited" followed by the AE number in parentheses, e.g., "Yes, Unsolicited (003)". If the finding was reported as a solicited AE, display "Yes, Solicited" followed by the symptom in parentheses, e.g., "Yes, Solicited (Nausea)". If the finding was from the screening visit, display "N/A" in the "Reported as an AE?" column. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. The footnotes should only include abbreviations appearing in the listing. Sort by Treatment Group, Participant ID, Actual Study Day, and Body System. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	Analysis Time Point	Actual Study Day	Body System	Abnormal Finding	Reported as an AE? (If Yes, Symptom or AE Number)
1 µg CJCV2	EHD.XXXXX	Screening (Study Day -30 to -2)	X	Abdomen	[finding]	No
1 µg CJCV2+ALFQ		Pre-Vaccination 1 (Study Day 1)		Cardiovascular/heart		Yes, Solicited ([symptom])
3 µg CJCV2		7 Days Post Vaccination 1 (Study Day 8)		Extremities		Yes, Unsolicited (XXX)
3 µg CJCV2+ALFQ		Pre-Vaccination 2 (Study Day 29)		General appearance		N/A
10 µg CJCV2		7 Days Post Vaccination 2 (Study Day 36)		HEENT		
10 µg CJCV2+ALFQ		Pre-Vaccination 3 (Study Day 57)		Lymph Nodes		
		7 Days Post Vaccination 3 (Study Day 64)		Musculoskeletal		
		28 Days Post Vaccination 3 (Study Day 85)		Neck		
		56 Days Post Vaccination 3 (Study Day 113)		Pulmonary/chest		
		Unscheduled Visit		Skin		

Note: AE = Adverse Event; HEENT = Head, Eyes, Ears, Nose, and Throat; N/A = Not Applicable.

16.2.10 Concomitant Medications

Listing 16: Concomitant Medications

[Implementation Note: "Medication Start" and "Medication End" are relative to first vaccination; the day of first vaccination is Study Day 1, and the day prior to first vaccination is Study Day -1. For medication start or end days more than 30 days prior to enrollment, categorize as follows: >5 years prior to enrollment, 1-5 years prior to enrollment, or 1-12 months prior to enrollment. If the medication is ongoing, display "Ongoing" in the "Medication End Day" column. If taken for a solicited AE, display "Yes, Solicited" in the "Taken for AE?" column. If taken for an unsolicited AE, display "Yes, Unsolicited" with the AE number in parentheses. If taken for MH, display "Yes" with the MH number in parentheses, e.g., "Yes (005)", in the "Taken for a condition on Medical History?" column. In the CSR, Participant ID should be USUBJID (not PATID) for purposes of de-identification. Sort by Treatment Group, Participant ID, and CM Number. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant ID	CM Number	Medication	Medication Start Day[a]	Medication End Day[a]	Indication	Taken for an AE? (AE Description;AE Number)	Taken for a condition on MH? (MH Description; MH Number)	ATC Level 1 (ATC Level 2)
1 µg CJCV2	EHD.XXXXX	XXX		> 5 years prior	> 5 years prior		No	No	
1 µg CJCV2+ALFQ				1-5 years prior	1-5 years prior		Yes, Solicited	Yes ([description]; XXX)	
3 µg CJCV2				1-12 months prior	1-12 months prior		Yes, Unsolicited ([description]; XXX)		
3 µg CJCV2+ALFQ				X	X				
10 µg CJCV2					Ongoing				
10 µg CJCV2+ALFQ									

Notes: CM = Concomitant Medication; AE = Adverse Event; MH = Medical History; ATC = Anatomical Therapeutic Chemical.
[a] Relative to study enrollment.

16.2.11 Pregnancy Reports

[Implementation Note: If no pregnancies are reported, all listings in this section will be replaced with text that states, "No pregnancies have been reported in Protocol 19-0003." There should be a black border around the text, and the text should be a minimum of 9 pt font.]

Listing 17: Pregnancy Reports – Maternal Information

[Implementation Note: The footnotes should only include abbreviations appearing in the listing. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Treatment Group	Participant 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?
1 µg CJCV2	EHD.XXXXX	X	X			X.X		No	No	No	No
1 µg CJCV2+ALFQ								Yes	Yes	Yes	Yes
3 µg CJCV2								Unknown	Unknown	Unknown	Unknown
3 µg CJCV2+ALFQ											N/A
10 µg CJCV2											
10 µg CJCV2+ALFQ											

Notes: N/A = Not Applicable.
Maternal Complications are included in the Adverse Event listing.
Medications taken during pregnancy are included in the Concomitant Medications Listing.

Listing 18: Pregnancy Reports – Gravida and Para

[Implementation Note: The footnotes should only include abbreviations appearing in the listing. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

			Live Births												
Participant 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?**
EHD.XXXXX	X	X	X	X	X	X	X	X	X	X	X	X	X	X	No
		U	U	U	U	U	U	U	U	U	U	U	U	U	Yes ([specify])
															U

Notes: U = Unknown.
Gravida includes the current pregnancy, para events do not.
[a] Preterm Birth
[b] Term Birth

Listing 19: Pregnancy Reports – Live Birth Outcomes

[Implementation Note: The footnotes should only include abbreviations appearing in the listing. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Participant ID	Pregnancy Number	Fetus Number	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?
EHD.XXXXX	X	X	No	Vaginal	XX weeks, X days	SGA	X	X	X.X	No	No
			Yes	Cesarean Section		AGA				Yes	Yes
			Unknown			LGA					Unknown
Notes: SGA = Small for Gestational Age; AGA = Appropriate for Gestational Age; LGA = Large for Gestational Age. Congenital Anomalies are included in the Adverse Event listing.											

Listing 20: Pregnancy Reports – Still Birth Outcomes

[Implementation Note: The footnotes should only include abbreviations appearing in the listing. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Participant ID	Pregnancy Number	Fetus Number	Study Day of Initial Report	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?
EHD.XXXXX	X	X	X	No	Vaginal	XX weeks, X days	SGA	X.X	No	No	Yes ([specify])
				Yes	Cesarean Section		AGA		Yes	Yes	No
				Unknown			LGA			Unknown	Unknown
											N/A

Notes: SGA = Small for Gestational Age; AGA = Appropriate for Gestational Age; LGA = Large for Gestational Age; N/A = Not Applicable.
Congenital Anomalies are included in the Adverse Event listing.

Listing 21: Pregnancy Reports – Spontaneous, Elective, or Therapeutic Abortion Outcomes

[Implementation Note: The footnotes should only include abbreviations appearing in the listing. Note that the values in the table are meant to represent possible values expected for that column and are not necessarily associated with entries in other columns in the same row.]

Participant ID	Pregnancy Number	Fetus Number	Study Day of Initial Report	Pregnancy Outcome (for this Fetus)	Gestational Age at Termination	Abnormality in Product of Conception?	Reason for Therapeutic Abortion
EHD.XXXXX	X	X	X	Spontaneous abortion/miscarriage	XX weeks, X days	No	Maternal condition/disease
				Elective abortion		Yes ([specify])	Fetal condition/disease
				Therapeutic abortion		Unknown	N/A
						N/A	

Note: N/A = Not Applicable.