CLINICAL RESEARCH IN INFECTIOUS DISEASES

STATISTICAL ANALYSIS PLAN
for
DMID Protocol: 18-0011

Study Title:

A Phase I Study to Assess the Safety, Reactogenicity and Immunogenicity of Two Quadrivalent Seasonal Influenza Vaccines (Fluzone® or Flublok®) With or Without One of Two Adjuvants (AF03 or Advax-CpG55.2) in Healthy Adults 18-45 Years of Age

NCT03945825

Version 3.0

DATE: 04 May 2021

STUDY TITLE

Protocol Number Code:	**DMID Protocol: 18-0011**
Development Phase:	Phase I
Products:	Sanofi 2018/2019 and 2019/2020 Fluzone Quadrivalent Influenza Vaccine (QIV) Sanofi 2018/2019 and 2019/2020 Flublok QIV Sanofi AF03 adjuvant Vaxine Advax- CpG55.2 adjuvant
Form/Route:	IM
Indication Studied:	Influenza
Sponsor:	Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health
Clinical Trial Initiation Date:	18 June 2019
Clinical Trial Completion Date:	18 September 2020
Date of the Analysis Plan:	04 May 2021
Version Number:	3.0

This study was performed in compliance with Good Clinical Practice.

TABLE OF CONTENTS

Table of Contents *(continued)*

Table of Contents *(continued)*

LIST OF ABBREVIATIONS

A/H1N1	Influenza A Virus of the H1N1 Subtype
A/H1N2v	Influenza A Virus of the H1N2 Variant Subtype
A/H2N2	Influenza A Virus of the H2N2 Subtype
A/H3N2	Influenza A Virus of the H3N2 Subtype
A/H3N2v	Influenza A Virus of the H3N2 Variant Subtype
A/H5N1	Influenza A Virus of the H5N1 Subtype
A/H5N6	Influenza A Virus of the H5N6 Subtype
A/H5N8	Influenza A Virus of the H5N8 Subtype
A/H7N1	Influenza A Virus of the H7N1 Subtype
A/H7N7	Influenza A Virus of the H7N7 Subtype
A/H7N9	Influenza A Virus of the H7N9 Subtype
A/H9N2	Influenza A Virus of the H9N2 Subtype
Advax	Trade name for delta inulin adjuvant formulation
AE	Adverse Event
AESIs	Adverse Events of Special Interest
AF03	Adjuvant formulation (03)
ALP	Alkaline phosphatase
ALT	Alanine Aminotransferase
ANCA	Anti-Neutrophil Cytoplasmic Antibody
AS03	Adjuvant System (03)
AST	Aspartate Aminotransferase
BP	Blood Pressure
BUN	Blood Urea Nitrogen
C	Celsius
CI	Confidence Interval
CpG55.2	Class B CPG oligonucleotide adjuvant
Cr	Creatinine
CRF	Case Report Form
DMID	Division of Microbiology and Infectious Diseases
DSMB	Data and Safety Monitoring Board

List of Abbreviations *(continued)*

EDC	Electronic Data Capture
ELISA	Enzyme-linked Immunosorbent Assay
ELISpot	Enzyme-Linked Immunosorbent Spot
ELLA	Enzyme-Linked Lectin Assay
ER	Emergency Room
ESR	Erythrocyte Sedimentation Rate
F	Fahrenheit
FDA	U.S. Food and Drug Administration
GCI	Global Clinical Immunology
GGT	Gamma-Glutamyl Transferase
GMT	Geometric Mean Titer
GMFR	Geometric Mean Fold Rise
HA	Hemagglutinin
HAI	Hemagglutination Inhibition Antibody
Hgb	Hemoglobin
HHS	U.S. Department of Health and Human Services
ICH	International Conference on Harmonisation
IIV	Inactivated Influenza Vaccine
IRB	Institutional Review Board
ITT	Intention to Treat
L	Liter
LLN	Lower Limit of Normal
MAAEs	Medically Attended Adverse Events
mcg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
mITT	Modified Intention to Treat
mL	Milliliter
MAR	Missing at Random
MCAR	Missing Completely at Random
MNAR	Missing Not at Random

List of Abbreviations *(continued)*

N, n	Number
NA	Neuraminidase
NAI	Neuraminidase Inhibition
Neut	Neutralizing Antibody
NIH	National Institutes of Health
NOCMCs	New-Onset Chronic Medical Conditions
PBMCs	Peripheral Blood Mononuclear Cells
PI	Principal Investigator
PIMMCs	Potentially Immune-Mediated Medical Conditions
PLT	Platelets
PP	Per Protocol
PT	Preferred Term
QIV	Quadrivalent Influenza Vaccine
RBC	Red Blood Cell
RCD	Reverse Cumulative Distribution
SAE	Serious Adverse Event
SD	Standard Deviation
SDCC	Statistical and Data Coordinating Center
SMC	Safety Monitoring Committee
SOC	System Organ Class
SP	Sanofi Pasteur
T. Bili	Total Bilirubin
TFH	T Follicular Helper
ULN	Upper Limit of Normal
ULOQ	Upper Limit of Quantitation
WBC	White Blood Cell
WHO	World Health Organization

1. PREFACE

The Statistical Analysis Plan (SAP) for "A Phase I Study to Assess the Safety, Reactogenicity and Immunogenicity of Two Quadrivalent Seasonal Influenza Vaccines (Fluzone® or Flublok®) With or Without One of Two Adjuvants (AF03 or Advax-CpG55.2) in Healthy Adults 18-45 Years of Age" (DMID Protocol 18-0011) describes and expands upon the statistical information presented in the protocol.

This document describes all planned analyses except transcriptomics analysis and provides reasons and justifications for these analyses. It also includes sample tables, figures, listings (TFLs) planned for (1) final analyses included in (1) the expedited report, (2) the Clinical Study Report (CSR). Regarding the final analyses and 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 U.S. 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, figures and listings (TFLs). Following any protocol amendment, this SAP will be reviewed and revised (if needed) to address any changes in the protocol impacting analysis. Any deviation from the final SAP will be described and justified in the CSR. 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

Influenza poses perpetual threats to human populations. Use of influenza vaccines is the primary means for preventing influenza. Current licensed inactivated influenza vaccines (IIVs) containing Hemagglutinin (HA) and Neuraminidase (NA) antigens are good for preventing influenza but are less effective than desirable. The inclusion of an adjuvant provides another mechanism to improve the immune response to IIV antigens.

The goal of this clinical trial is to assess in healthy adults, 18-45 years of age, the safety, reactogenicity and immunogenicity of one dose of 2018/2019 Quadrivalent Influenza Vaccine (either Fluzone or Flublok) administered intramuscularly (IM) with or without one of two adjuvants (AF03 or Advax-CpG55.2). The study will evaluate the traditional Hemagglutination Inhibition (HAI) and Neutralizing or Neutralization (Neut) responses among groups, but also will explore additional immunological parameters. Since antibodies targeting the NA may represent an independent correlate of protection against influenza infection, we plan to assess the Neuraminidase Inhibiting or Inhibition (NAI) responses in each group. The longitudinal kinetics and durability of HAI, Neut, and NAI responses will be evaluated for one year following vaccination.

This clinical trial will also assess cellular correlates of immunity to influenza including memory B cell populations, plasmablasts, TFH cells, functional non-neutralizing Fc-effector antibodies, as well as determine the transcriptional profiling responses following vaccination.

2.1. Purpose of the Analyses

These analyses will assess the safety and immunogenicity of one dose of 2018/2019 Quadrivalent Influenza Vaccine (either Fluzone or Flublok) administered IM with or without one of two adjuvants (AF03 or Advax-CpG55.2) and will be included in the expedited report and clinical study report.

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives and Outcome Measures

Primary Safety Objectives	**Primary Safety Outcome Measures**
• To assess the safety and reactogenicity of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• Occurrence of solicited injection site and systemic reactogenicity events through approximately Day 8 after the first study vaccination. • Occurrence of unsolicited adverse events from the time of the first study vaccination through approximately Day 29. • Occurrence of all SAEs through approximately 12 months following receipt of the first study vaccination. • Occurrence of abnormal clinical safety laboratory AEs from the time of study vaccination through approximately Day 8 after the first study vaccination.
Primary Immunogenicity Objectives	**Primary Immunogenicity Outcome Measures**
• To assess the serum hemagglutination inhibition (HAI) antibody responses against 2018/2019 QIV strains from baseline (Day 1) to approximately Day 29 after receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving HAI titer seroconversion against the 2018/2019 QIV strains (defined as either a pre-vaccination titer <1:10 and a post-vaccination titer ≥1:40 **or** a pre-vaccination titer ≥1:10 and a minimum four-fold rise in post-vaccination antibody titer) on approximately Day 29 for each study group. • The percentage of subjects with an HAI titer ≥1:40 against the 2018/2019 QIV strains at baseline and approximately Day 29 for each study group. • Geometric mean titers (GMTs) of serum HAI against the 2018/2019 QIV strains at baseline and approximately Day 29 for each study group.

	• Ratio of GMTs of serum HAI against the 2018/2019 QIV strains between adjuvanted and unadjuvanted study groups at baseline and approximately Day 29. • Geometric mean fold rise (GMFR) in HAI titers from baseline (Day 1) against the 2018/2019 QIV strains at approximately Day 29 for each study group
• To assess the serum neuraminidase inhibition antibody (NAI) responses by enzyme-linked lectin assay (ELLA) against NA antigens in the 2018/2019 QIV from baseline (Day 1) to approximately Day 29 after receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving NAI seroconversion (defined as ≥4-fold rise in post vaccination antibody titers against the NA antigens in the 2018/2019 QIV) on approximately Day 29 for each study group. • The serum NAI GMT at baseline (Day 1) and approximately Day 29 for each study group. • Ratio of serum NAI GMT between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Day 29. • Geometric mean fold rise (GMFR) in NAI titers from baseline (Day 1) against NA antigens in the 2018/2019 QIV strains at approximately Day 29 for each study group
• To assess the influenza neutralizing (Neut) antibody titer responses against 2018/2019 QIV strains from baseline (Day 1) to approximately Day 29 after receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax- CpG55.2 adjuvant.	• The percentage of subjects achieving Neut titer seroconversion against the 2018/2019 QIV strains (defined as either a pre-vaccination titer <1:10 and a post-vaccination titer ≥1:40 **or** a pre-vaccination titer ≥1:10 and a minimum four-fold rise in post-vaccination antibody titer) on approximately Day 29 for each study group. • The percentage of subjects with a Neut titer ≥1:40 against the 2018/2019 QIV strains at baseline (Day 1) and approximately Day 29 for each study group. • Serum Neut GMT at baseline (Day 1) and approximately Day 29 for each study group

	• Ratio of serum Neut GMT between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Day 29. • Geometric mean fold rise (GMFR) in Neut titers from baseline (Day 1) against the 2018/2019 QIV strains at approximately Day 29 for each study group
Secondary Safety Objectives	**Secondary Safety Outcome Measures**
• To assess protocol specified AESIs, medically-attended adverse events (MAAEs), including new-onset chronic medical conditions (NOCMCs) and potentially immune-mediated medical conditions (PIMMCs) that occur after receipt of study product.	• Occurrence of all protocol specified AESIs, MAAEs, including NOCMCs and PIMMCs, from the time of the first study vaccination through approximately 12 months following the first vaccination.
Secondary Immunogenicity Objectives	**Secondary Immunogenicity Outcome Measures**
• To assess the HAI, Neut and NAI ELLA responses to the 2019/2020 QIV strains prior to (Day 1) and approximately 28 days after vaccination with the 2019/2020 QIV in all study groups	• The percentage of subjects achieving an HAI titer ≥1:40 against 2019/2020 QIV strains approximately on Days D90 (baseline) and D118 (28 days post-2019/2020 vaccine) for each study group. • The percentages of subjects achieving HAI, Neut and NAI titer seroconversion, against 2019/2020 QIV strains on approximately Day 118 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Serum Neut, HAI and NAI GMTs against 2019/2020 QIV strains approximately on Days D90 (baseline) and D118 (28 days post-2019/2020 QIV) for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Ratio of serum Neut, HAI and NAI GMTs against 2019/2020 QIV strains between adjuvanted and unadjuvanted study groups approximately on Days D90 (baseline) and D118 (28 days post-2019/2020 QIV). NAI

	titers will only be assessed on study groups 1,2 and 3. • Serum Neut, HAI and NAI GMFRs against 2019/2020 QIV strains from baseline (D90) on approximately D118 for each study group (NAI titers will only be assessed on study groups 1,2 and 3).
• To assess the HAI antibody responses against heterologous influenza A/H1 and H3 strains from baseline (Day 1) to approximately Days 8, 29, 57, 90, and 118 after receipt of 2018/2019 Fluzone or Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentages of subjects achieving HAI titer seroconversion, against heterologous H1 and H3 influenza strains on approximately Days 8, 29, 57, 90, and 118 for each study group. • The percentage of subjects achieving an HAI titer ≥1:40 against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118 for each study group. • Serum HAI GMT against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118 for each study group. • Ratio of serum HAI GMT against heterologous H1 and H3 influenza strains between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118. • Geometric mean fold rise (GMFR) in HAI from baseline (Day 1) against heterologous H1 and H3 influenza strains at approximately Days 8, 29, 57, 90, and 118 for each study group
• To assess NAI ELLA responses against heterologous N1 and N2 NA antigens from baseline (Day 1) to approximately Days 8, 29, 57, 90, and 118 after administration of 2018/2019 Fluzone with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving seroconversion against heterologous N1 and N2 NA antigens on approximately Days 8, 29, 57, 90, and 118 for study groups 1, 2 and 3. • Serum NAI GMTs against heterologous N1 and N2 NA antigens at baseline and

	approximately Days 8, 29, 57, 90, and 118 for study groups 1, 2 and 3. • Ratio of serum NAI GMTs against heterologous N1 and N2 NA antigens between adjuvanted and unadjuvanted study groups at baseline and approximately Days 8, 29, 57, 90, and 118 (NAI titers will only be assessed on study groups 1,2 and 3). • Geometric mean fold rise (GMFR) in serum NAI from baseline against heterologous N1 and N2 NA antigens at baseline and approximately Days 8, 29, 57, 90, and 118 for study groups 1, 2 and 3.
• To assess the influenza neutralizing (Neut) antibody titer responses against heterologous influenza A/H1 and H3 strains from baseline (Day 1) to approximately Days 8, 29, 57, 90, and 118 after administration of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving Neut titer seroconversion against heterologous H1 and H3 influenza strains on approximately Days 8, 29, 57, 90, and 118 for each study group. • Serum Neut GMT against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118 for each study group. • Ratio of serum Neut GMT against heterologous H1 and H3 influenza strains between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118. • Geometric mean fold rise (GMFR) of neut antibody titers from baseline against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 8, 29, 57, 90, and 118 for each study group.
• To assess the longitudinal kinetics and durability of the HAI, NAI, and Neut responses against the 2018/2019 QIV strains on approximately Days 8, 57, 90,	• The percentage of subjects achieving HAI, NAI and Neut titer seroconversion against 2018/2019 QIV antigens and strains on approximately Days 8, 57, 90, and 118 for

and 118 following receipt of the 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	each study group (NAI titers will only be assessed on study groups 1,2 and 3). • The percentage of subjects achieving an HAI and Neut titer ≥1:40 against 2018/2019 QIV strains on approximately Days 8, 57, 90, and 118 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Serum Neut, HAI and NAI GMT against 2018/2019 QIV strains on approximately Days 8, 57, 90, and 118 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Ratio of serum Neut, HAI and NAI GMT against 2018/2019 QIV strains between adjuvanted and unadjuvanted study groups on approximately Days 8, 57, 90, and 118 (NAI titers will only be assessed on study groups 1,2 and 3). • Geometric mean fold rise (GMFR) in HAI, Neut and NAI titers from baseline (Day 1) against the 2018/2019 QIV strains at approximately Day 8, 57, 90, and 118 for each study group (NAI titers will only be assessed on study groups 1,2 and 3).
Exploratory Immunogenicity Objectives	**Exploratory Immunogenicity Study Outcomes**
• To assess the HAI antibody responses against heterologous influenza A/H1 and H3 strains from baseline (Day 1) to approximately Days 180 and 365 after receipt of 2018/2019 Fluzone or Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentages of subjects achieving HAI titer seroconversion, against heterologous H1 and H3 influenza strains on approximately Days 180 and 365 for each study group. • The percentage of subjects achieving a HAI titer ≥1:40 against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 180 and 365 for each study group. • Serum HAI GMT against heterologous H1 and H3 influenza strains at baseline (Day 1)

	and approximately Days 180 and 365 each study group. • Ratio of serum HAI GMT against heterologous H1 and H3 influenza strains between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Days 180 and 365. • Geometric mean fold rise (GMFR) in HAI from baseline (Day 1) against heterologous H1 and H3 influenza strains at approximately Days 180 and 365 for each study group
• To assess NAI ELLA responses against heterologous N1 and N2 NA antigens from baseline (Day 1) to approximately Days 180 and 365 administration of 2018/2019 Fluzone with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving seroconversion against heterologous N1 and N2 NA antigens on approximately Days 180 and 365 for study groups 1, 2 and 3. • Serum NAI GMTs against heterologous N1 and N2 NA antigens at baseline and approximately Days 180 and 365 for study groups 1, 2 and 3. • Ratio of serum NAI GMTs against heterologous N1 and N2 NA antigens between adjuvanted and unadjuvanted study groups at baseline and approximately Days 180 and 365 for study groups 1,2 and 3. • Geometric mean fold rise (GMFR) in serum NAI from baseline against heterologous N1 and N2 NA antigens at baseline and approximately Days 180 and 365 for study groups 1, 2 and 3.
• To assess the influenza neutralizing (Neut) antibody titer responses against heterologous influenza A/H1 and H3 strains from baseline (Day 1) to approximately Days 180 and 365 after administration of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving Neut titer seroconversion against heterologous H1 and H3 influenza strains on approximately Days 180 and 365 for each study group. • Serum Neut GMT against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 180 and 365 for each study group.

	• Ratio of serum Neut GMT against heterologous H1 and H3 influenza strains between adjuvanted and unadjuvanted study groups at baseline (Day 1) and approximately Days 180 and 365. • Geometric mean fold rise (GMFR) of neut antibody titers from baseline against heterologous H1 and H3 influenza strains at baseline (Day 1) and approximately Days 180 and 365 for each study group.
• To assess the longitudinal kinetics and durability of the HAI, NAI, and Neut responses against the 2018/2019 QIV strains on approximately Days 180 and 365 following receipt of the 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The percentage of subjects achieving HAI, NAI and Neut titer seroconversion against 2018/2019 QIV antigens and strains on approximately Days 180 and 365 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • The percentage of subjects achieving an HAI and Neut titer ≥1:40 against 2018/2019 QIV strains on approximately Days 180 and 365 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Serum Neut, HAI and NAI GMT against 2018/2019 QIV strains on approximately Days 180 and 365 for each study group (NAI titers will only be assessed on study groups 1,2 and 3). • Ratio of serum Neut, HAI and NAI GMT against 2018/2019 QIV strains between adjuvanted and unadjuvanted study groups on approximately Days 180 and 365 (NAI titers will only be assessed on study groups 1,2 and 3). • Geometric mean fold rise (GMFR) in HAI, Neut and NAI titers from baseline (Day 1) against the 2018/2019 QIV strains at approximately Day 180 and 365 for each study group (NAI titers will only be assessed on study groups 1,2 and 3).
• To assess the HAI, Neut and NAI ELLA responses to the 2018/2019 at all timepoints	• The percentage of subjects achieving an HAI titer ≥1:40 against 2018/2019 QIV strains at

and 2019/2020 QIV strains prior to and approximately 28 days after vaccination with the 2019/2020 QIV in all study groups, according to serostatus at baseline and previous influenza vaccination	all timepoints and against 2019/2020 QIV strains at approximately D90 and D118. • The percentages of subjects achieving HAI, Neut and NAI titer seroconversion, against 2018/2019 QIV strains at approximately D29 and against 2019/2020 QIV strains at approximately D118. • Serum Neut, HAI and NAI GMTs against 2018/2019 QIV strains at all timepoints (for study groups 4, 5 and 6 NAI titers will only be assessed at D1 and D29) and against 2019/2020 QIV strains at approximately D90 and D118 (NAI titers will only be assessed on study groups 1,2 and 3). • Serum Neut, HAI and NAI GMFRs against 2018/2019 QIV strains on approximately Days 8, 29, 57, 90, 118, 180 and 365 (for study groups 4, 5 and 6 NAI titers will only be assessed at D1 and D29) and against 2019/2020 QIV strains at approximately D118 (NAI titers will only be assessed on study groups 1,2 and 3).
• To assess B Cell effector and memory responses prior to (Day 1) and following receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• Change in the frequency of influenza specific-IgG, IgM and IgA B memory cells using multiplexed FluoroSpot from baseline (Day 1) to approximately Days 29 and 90 for each study group. • Change in frequency of influenza-specific IgG, IgM and IgA effector B cells (plasmablast) using multiplexed FluoroSpot from baseline (Day 1) to approximately Day 8 for each study group.
• To assess plasmablast and T follicular helper (Tfh cell responses prior to (Day 1) and following receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• Change in the frequency of plasmablast and Tfh cells using multiparametric flow cytometry from baseline (Day 1) to approximately Day 8 for each study group.
• To assess the functional non-neutralizing Fc-effector antibody responses prior to (Day 1) and following receipt of 2018/2019	• GMT of functional non-neutralizing Fc-effector antibodies against vaccine strain antigens at baseline (Day 1) and

Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	approximately Day 29 after vaccination for each study group. • Geometric mean fold rise (GMFR) in functional non-neutralizing Fc-effector antibody titers from baseline (Day 1) against the 2018/2019 QIV strains at approximately Day 29 for each study group
• To assess responses from baseline (Day 1) in transcriptomic profiling on approximately Days 2 and 8 following receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• Differential expression of transcription profiles comparing samples taken just prior to (Day 1) and on approximately Days 2 and 8 following receipt of the 2018/2019 QIV vaccination in at least a subset of subjects for each study group.
• To evaluate the relationship of non-neutralizing Fc-effector antibodies titers with HAI and NA responses following receipt of 2018/2019 Fluzone and Flublok with and without AF03 or Advax-CpG55.2 adjuvant.	• The association of non-neutralizing Fc-effector antibodies GMT with HAI and Neut antibody GMT, seroprotection and seroconversion rates to variant influenza strains and the 2018/2019 QIV vaccine strains.
• To describe the non-neutralizing Ab responses to different influenza HA antigens by a multiplex ELISA assay at all time points in each study group	• Quantification of HA binding antibodies against different influenza HA antigens at baseline (Day 1) and Days 8, 29, 57, 90, 118, 180 and 365 in each study group.
• To describe the NA binding antibody response to NA antigens corresponding to the vaccine strain antigens by an ELISA assay after administration of Fluzone with and without AF03 or Advax-CpG55.2 adjuvant.	• Quantification of NA binding antibodies against influenza NA antigens corresponding to the vaccine strain antigens at baseline (Day 1), Day 29, 57, 90 and D118 in Groups 1, 2, 3. Additional studies on Days180 and 365 in Groups 1,2,3 will be contingent on seeing increased seroconversion rates to homologous vaccine strain antigens

3.2. Study Definitions and Derived Variables

For individual subjects, fold rise will be calculated as the ratio of: $\frac{post-vaccination\ titer}{pre-vaccination\ titer}$, where pre-vaccination value is the result obtained at Day 1 prior to the priming dose. However, for assay results against 2019/2020 QIV strains, pre-vaccination titer is the result obtained at Day 90.

HAI Seroconversion is defined as either a pre-vaccination titer <1:10 and a post-vaccination titer ≥1:40 **or** a pre-vaccination titer ≥1:10 and a minimum four-fold rise in post-vaccination antibody titer [1].

NAI seroconversion is defined as ≥4-fold rise in post vaccination antibody titers against the NA antigens in the 2018/2019 QIV.

Neut Seroconversion is defined as either a pre-vaccination titer <1:10 and a post-vaccination titer ≥1:40 **or** a pre-vaccination titer ≥1:10 and a minimum four-fold rise in post-vaccination antibody titer.

Seronegative baseline status is defined as pre-vaccination antibody titer of ≤1:10.

Seropositive baseline status is defined as pre-vaccination antibody titer of >1:10.

For HAI and Neut assays, Seroprotection is defined as titer ≥ 40.

4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

DMID Protocol 18-0011 follows a Phase I randomized, double blind study design enrolling males and non-pregnant females aged 18-45 years of age, inclusive, who are in good health as determined by medical history and physical examination, and meet all eligibility criteria, including erythrocyte sedimentation rate (ESR) and negative urine or serum pregnancy test (for females). This clinical trial is designed to assess the safety, reactogenicity and immunogenicity of either the 2018/2019 Fluzone or Flublok Quadrivalent Influenza Vaccines (QIV), manufactured by Sanofi Pasteur (SP) given without adjuvant or with one of two adjuvant formulations, AF03 (SP) or Advax-CpG55.2 (Vaxine Pty Ltd).

In this trial, subjects will be stratified by prior receipt of licensed, seasonal influenza vaccine (defined as receipt of at least one of the 2017/2018 and/or 2018/2019 influenza vaccines) and will be randomly assigned to 1 of 6 study arms to receive a single dose of one of the two seasonal 2018/2019 QIV vaccine formulations with or without one of the two adjuvants (Day 1). On approximately Day 90, each subject will receive a single dose of the seasonal 2019/2020 influenza vaccine. Treatment will be assigned to each study arm as described in Table 1.

To determine early safety signals for this Phase I study, enrollment will proceed in a staged fashion for the first 6 sentinel subjects. The first six subjects will be randomized and vaccinated with one each from Groups 1-6. These six subjects will be followed through Day 8. If any of the pre-specified halting rules for the sentinel subjects occur, the study will be halted and reviewed by the DSMB. If no pre-specified safety signals are encountered enrollment will proceed.

The DSMB will review the data when the 8-day reactogenicity and clinical safety laboratory data following the first study vaccination are available for 50% of study subjects. Enrollment will not be paused for this review. An additional scheduled DSMB review will occur when all HAI, NAI and Neut data for Day 1, and Day 29 and safety data through Day 57 following the first study vaccination, are available.

Reactogenicity will be measured by the occurrence of solicited injection site and systemic reactions from the time of the first study vaccination through Day 8. Unsolicited non-serious adverse events (AEs) will be collected from Day 1 through approximately Day 29. Serious adverse events (SAEs); Adverse Events of Special Interest (AESIs) including reports of tearing, dry mouth, dry eyes; medically-attended adverse events (MAAEs), new-onset chronic medical conditions (NOCMCs); and potentially immune-mediated medical conditions (PIMMCs), will be collected Day 1 through approximately 12 months after the first study vaccination. Clinical safety laboratory evaluations (hematology and chemistry) will be performed at screening, immediately prior to the first study vaccination, and at approximately Day 8.

Immunogenicity testing will include performing serological assays to assess hemagglutination inhibition (HAI), neutralizing (Neut), and neuraminidase inhibition (NAI) titers at multiple time points following both study vaccinations. Antibody responses will be determined for both influenza vaccine strains and heterologous influenza strains. Additional exploratory immunologic responses will include longitudinal assessments of the kinetics, magnitude, specificity, and/or quality of influenza-specific memory B cells, plasmablasts, circulating T follicular helper (TFH) cells, and non-neutralizing antibody responses to HA and NA antigens (Multiplex ELISA, NA ELISA, Systems Serology).

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

This study uses a dose comparison concurrent control design. All subjects receive the same study product (2018/2019 Fluzone or Flublok QIV) with or without adjuvants on Day 1. On Day 90, all subjects receive the seasonal vaccine of either Fluzone 2019/2020 QIV or Flublok 2019/2020 QIV.

4.3. Selection of Study Population

The study population for this clinical trial is 240 males and non-pregnant females, 18-45 years old, who are in good health and meet all eligibility criteria. The subjects will be recruited from the general population at the participating Vaccine Trial and Evaluation Unit (VTEU) sites that have substantial experience conducting large influenza vaccine studies.

4.4. Treatments

4.4.1. Treatments Administered

2018/2019 Flublok QIV, 2018/2019 Fluzone QIV, 2019/2020 Flublok QIV, 2019/2020 Fluzone QIV, AF03 adjuvant, and Advax-CpG55.2 adjuvant will be administered.

4.4.2. Identity of Investigational Product(s)

See the study protocol for details of study product formulation.

4.4.3. Method of Assigning Subjects to Study Arms (Randomization)

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

Eligible subjects will be stratified by clinical site and prior receipt of licensed, seasonal influenza vaccine (defined as receipt of at least one of the 2017/2018 and/or 2018/2019 influenza vaccines) and randomly assigned with allocation (1:1:1:1:1:1) to one of 6 study arms indicated in Table 1. The treatment sequence was generated using permuted block randomization to provide an approximately balanced allocation to the study arms during the study.

4.4.4. Selection of Doses in the Study

Each subject will receive a dose of either 2018/2019 Fluzone QIV or 2018/2019 Flublok QIV on Day 1 and a dose of 2019/2020 Fluzone QIV or 2019/2020 Flublok QIV on approximately day 90.

- 2018/2019 and 2019/2020 Flublok QIVs are formulated to contain 180 µg of HA per 0.5 mL dose, with 45 µg of HA derived from each of four influenza virus strains recommended for the 2018/2019.
- 2018/2019 and 2019/2020 Fluzone QIVs are formulated to contain 60 µg of HA per 0.5 mL dose with 15 µg of HA from each of the four influenza virus strains.
- Each 0.25mL dose of AF03 that will be administered admixed with vaccine contains approximately 12.5 mg of squalene
- Each Advax-CpG55.2 adjuvant will be made of two components Advax (delta inulin) and CpG55.2. Each 2.0 mL vial contains 0.5 mL of a 50 mg/mL suspension of delta inulin in phosphate buffered saline and 0.5 mL of a 2 mg/mL solution of CpG55.2.

4.4.5. Selection and Timing of Dose for Each Subject

Each subject is to be randomly assigned to a study group which will define the type and dose of 2018/2019 QIV and adjuvant that they will receive. The first vaccination takes place on the day of randomization. On approximately Day 90 after the first vaccination (protocol defined window of Day 90 +/- 14 days post first vaccination), each subject will receive a single dose of the seasonal 2019/2020 influenza vaccine. This dosing interval was selected so receipt of the 2019/2020 dose would fall within the recommended timeframe for season vaccination.

4.4.6. Blinding

This trial is double-blinded; subjects, investigators, study personnel performing any study-related assessments following study vaccine administration, and laboratory personnel performing antibody assays are blinded to dosage within study vaccination schedule.

The randomization scheme was generated by the SDCC and provided to unblinded study personnel (i.e., pharmacists performing study vaccination preparations and unblinded study vaccine administrators) at the participating VTEU sites who will not be involved in study-related assessments or have subject contact for data collection following study vaccine administration.

The Data and Safety Monitoring Board (DSMB) may receive data in aggregate and presented by group. The DSMB may also be provided with expected and observed rates of the expected AEs in an unblinded fashion and may request treatment assignment be unblinded for an individual subject if required for safety assessment. The DSMB will review grouped and unblinded data in the closed session only.

4.4.7. Prior and Concomitant Therapy

Administration of any medications, therapies, or vaccines (including prescription and over-the-counter drugs as well as herbals, vitamins, and supplements) from 60 days prior to study vaccination through 21 days post final vaccination will be solicited from the participant during screening, enrollment, and follow-up. Any reported prior therapies from up to 30 days prior to vaccination through 28 days post first study vaccination will be recorded in the appropriate data collection form.

Use of concomitant medications is allowed prior to and during the trial with the exception of medications and therapies that might interfere with the evaluation of the investigational product. Medications in this category include the prohibited medication per the Subject Exclusion Criteria (protocol Section 5.1.2). In addition, the site principal investigator or appropriate sub-investigator may identify other medications that should not be used due to a risk to subject safety or assessment of reactogenicity and immunogenicity.

4.4.8. Treatment Compliance

All subjects were to receive two doses of study product administered in the clinic.

4.5. Efficacy (Immunogenicity) and Safety Variables

See Table 2 for schedule of study procedures.

4.5.1. Safety Variables

Safety will be assessed by the frequency and severity of:

1. SAEs occurring from the time of the first study vaccination through approximately 12 months after the first study vaccination.
2. Solicited AEs – reactogenicity events occurring from the time of study vaccination through approximately Day 8 after the first study vaccination.
    a. Injection site reactions including pruritus, ecchymosis, erythema, induration/swelling, edema, pain, and tenderness.
    b. Systemic reactions including fever, feverishness, fatigue, malaise, myalgia, arthralgia, headache, and nausea.
3. Clinical safety laboratory AEs occurring from the time of the first study vaccination through approximately Day 8 after the first study vaccination. Parameters to be evaluated include white blood cells (WBC), hemoglobin (Hgb), platelets (PLT), alanine aminotransferase (ALT), total bilirubin (T. Bili), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP) serum lipase and serum amylase and creatinine (Cr).
4. Unsolicited AEs – non-serious AEs occurring from the time of the first study vaccination through approximately Day 29 after the first study vaccination.
5. All protocol specified AESIs, MAAEs, NOCMCs and PIMMCs, from the time of the first study vaccination through approximately 12 months following the first.

Grading scales for injection site and systemic solicited reactions, vital signs, and clinical laboratory parameters are provided in Table 7, Table 8, Table 9, and Table 10.

4.5.2. Immunogenicity Variables

Individual HAI assay results against the 2018/2019 QIV strains, 2019/2020 QIV strains, and heterologous H3 influenza strains (A/Kenya/105/2017 [H3N2], A/Louisiana/13/2017 [H3N2], A/Aksaray/4048/2016 [H3N2], A/Shandonglaicheng/1763/2016 [H3N2], and A/Michigan/84/2016 [H3N2]) will be performed at Q2 Solution laboratory under the responsibility of GCI and results will be reported by GCI.

Individual Neut assay results will be performed and reported by Global Clinical Immunology (GCI) lab at Sanofi Pasteur laboratory for the 2018/2019 QIV strains, 2019/2020 QIV strains, and heterologous H3 influenza strains (A/Kenya/105/2017 [H3N2], A/Louisiana/13/2017 [H3N2], A/Aksaray/4048/2016 [H3N2], A/Shandonglaicheng/1763/2016 [H3N2], and A/Michigan/84/2016 [H3N2]).

Individual NAI results against the 2019/2020 QIV strains, 2018/2019 QIV strains, and heterologous N1 and N2 NA antigens (A/OMAN/5532/2017, A/CAMEROON/9766/2017, A/Human/Hubei/3/2005, A/LOUISIANA/13/2017, A/TOWNSVILLE/51/2016, A/AKSARAY/4048/2016) will performed by Q2 Solution laboratory under the responsibility of GCI and the data will be reported by GCI.

HAI, NAI, and Neut assay results are reported as a reciprocal titer with values of $10*2^k$, where k=0, 1, 2, etc. The lower limit of detection for the HAI, NAI and Neut assays is 1:10; values below the limit of detection are reported as '<10', and for analysis are imputed as one-half the limit of detection (10/2 = 5). The upper limit of quantitation (ULOQ) varies by assay and strain. Values above the upper limit of quantitation will be reported as '>=ULOQ', and for analysis are imputed as the upper limit of quantitation (ULOQ). HAI, NAI, and Neut

assays will be done in duplicates. Both titers will be reported for the HAI and NAI assays, but only one Geometric Mean Titer (GMT) will be reported for Neut assay. For analysis of HAI and NAI, the geometric mean (calculated on natural log scale) of repeated results for each sample will be computed and used as the response for all subsequent calculations. The variation arising from multiple measurements for an individual at a single time point is not used in subsequent calculations. See Section 3.2 for definitions of derived variables for the analysis of HAI, NAI, and Neut data.

Influenza-specific IgG, IgM, and IgA memory B cells using Multiplex FluoroSpot assay will be performed by Caprion Biosciences Inc. These assay results are reported as Spot Forming Cells (SCF) per million PBMC. Two or three replicated will be reported.

Influenza specific plasmablasts using multiparametric flow cytometry will be reported by SP-VaxDesign. The results will be measured in "Arbitrary Units/ml" against serum standard curve. One or two replicates will be provided.

Influenza specific Tfh cells using multiparametric flow cytometry will be reported by SP-VaxDesign. Percent Tfh and number of Tfh will be reported, and one or two replicates will be provided.

Functional non-neutralizing Fc-effector results will be reported by SeromYx Inc.

Assay results for quantification of HA binding antibodies against different influenza H3 strains obtained by Antibody Forensic Technology using multiplex ELISA and NA binding antibodies against different influenza NA antigens from ELISA will be reported by Sanofi Pasteur FluNXT Immunology laboratory. No repeats will be performed; one result will be reported.

All immunogenicity data will be uploaded into the SDCC's electronic data capture system.

5. SAMPLE SIZE CONSIDERATIONS

This study is planned to enroll a total of 40 subjects in each group. This study is not designed to test a formal null hypothesis. Rather, it is intended to obtain sufficient data to obtain meaningful estimates of the immune response and to uncover any safety issues that occur at a sufficiently high rate that they might be observed in a study of this size. As such, the type one error rate, alpha = 0.05, is not adjusted for multiple comparisons. While this study is not designed to test any specific null hypothesis, the following tables illustrate the precision and power that is available for select estimates and comparisons of interest.

Table 3 indicates the probability of observing one or more safety events, such as solicited injection site or systemic reactogenicity events or an unsolicited non-serious AE of a particular type for sentinel subjects (N=4 or 6), for a single adjuvanted/ unadjuvanted study arm/stratum (N = 40 or 60), for all subjects receiving the same seasonal QIV (N= 120), for all subjects in the trial (N=240).

Binomial confidence intervals (CI) are widest (have the least precision) when the response rate is 50%. Table 4 is presented to indicate the worst-case scenario for precision of observed exact (Clopper-Pearson) binomial confidence intervals.

Table 5 illustrates the minimum detectable differences in the proportion of subjects responding (e.g., attaining seroconversion or a titer ≥1:40) between two adjuvanted study arms using a two-sided Likelihood Ratio Test and alpha = 0.05.

6. GENERAL STATISTICAL CONSIDERATIONS

6.1. General Principles

Unless otherwise specified, all continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. In general, all data will be listed, sorted by treatment and subject, and when appropriate by visit number within subject. All summary tables will be structured with a column for each study arm in the following order:

- Group 1: Fluzone
- Group 2: Fluzone + AF03
- Group 3: Fluzone + Advax-CpG
- Group 4: Flublok
- Group 5: Flublok + AF03
- Group 6: Flublok + Advax-CpG

All tables will be annotated with the total population size relevant to that table/treatment, including any missing observations.

6.2. Timing of Analyses

6.2.1. Expedited Report

Clinical, safety, and reactogenicity data through approximately 56 days after study vaccination will represent the interim clinical database for this trial. Once the last subject completes the visit that occurs approximately 56 days after first study vaccination, the interim clinical database will be cleaned, monitored, and locked. Upon receipt of immunogenicity data for Day 1 and Day 29 (HAI, NAI, and Neut against 2018/2019 QIV strains and heterologous strains) and safety data through Day 57, the sponsor will authorize the SDCC to transfer to Sanofi Pasteur a copy of this unblinded data set. An Expedited Report containing analyses of safety data through Day 57 and HAI, NAI, and Neut data for 2018/2019 QIV strains from baseline (Day 1) and Day 29 unblinded by study arm only will be prepared by the SDCC. These analyses may be made available to the sponsor and pharmaceutical partners for planning subsequent trials as well as to the DSMB for review.

The analyses performed for the Expedited Report or using the data set provided to Sanofi Pasteur will not be used to make any decisions concerning the conduct of this trial. As it is anticipated that subjects will remain in long term safety follow-up at the time of these analyses, blinded investigators and DMID medical monitors not involved in the analysis, publication, or Expedited Report preparation will be responsible for assessing SAEs and AESIs (including Protocol Specified AESIs, MAAEs, NOCMCs and PIMMCs) until all subjects have completed the final follow-up visit.

Tables to be included in the Expedited Report are indicated with the symbol * in the title in Appendix 1.

6.2.2. Clinical Study Report

The final CSR will be completed after the last subject's last visit is completed, and the final clinical database including all long-term safety follow-up data is cleaned, monitored and locked, and all primary and secondary immunogenicity data are available. After such data are reported in the database and the data are considered clean and complete, a "topline" subset of the immunogenicity tables planned for the CSR will be provided to DMID and Sanofi Pasteur. These tables are indicated with a ¥ symbol after the title in the appendix.

Analysis of exploratory immunogenicity endpoints may be performed and released as the data are available from the research laboratory. Any such analyses would be considered the final analysis for the endpoint and included in the CSR. Additional exploratory immunogenicity endpoint data not available at the time of CSR preparation may be included in an addendum to the CSR, manuscript(s), or other report.

6.3. Analysis Populations

6.3.1. Safety Population

The Safety Analysis population includes all subjects who received the first study vaccination. For all safety analyses subjects will be grouped based on actual vaccination(s) received.

6.3.2. Modified Intention-to-Treat (mITT) Population

The modified intent-to-treat (mITT) population includes all randomized subjects who received the first study vaccination and contributed at least one post-first study vaccination venous blood samples for immunogenicity testing (HAI, NAI or Neut antibody assays) for which valid results were reported. For analyses using the mITT population, subjects will be grouped based on randomized study arm.

6.3.3. Per Protocol Population

The per protocol (PP) population includes all subjects in the mITT with the following exclusions:

- Data from all available visits for subjects found to be ineligible at baseline.
- Data from all visits for subjects that did not contribute venous blood samples for immunogenicity testing (HAI, NAI or Neut antibody assays) at baseline (Day 1).
- Data from all visits subsequent to major protocol deviations or events, in the opinion of the principal investigator and DMID scientific lead, expected to impact immune response such as:
    - Receipt of non-study licensed live vaccine within 30 days before or after study vaccination,
    - Receipt of non-study licensed inactivated vaccine within 14 days before or after study vaccination,
    - Receipt of immunosuppressive therapy (e.g., corticosteroids) within 30 days before or after the first study vaccination.
- Data from any visit that occurs out of window by more than one day:
    - Visit 2 data collected before Day 2 or after Day 4 post study vaccination.
    - Visit 3 data collected before Day 6 or after Day 10 post study vaccination.
    - Visit 4 data collected before Day 26 or after Day 32 post study vaccination.

- Visit 5 data collected before Day 53 or after Day 61 post study vaccination
- Visit 6 data collected before Day 75 or after Day 105 post study vaccination.
- Visit 7 data collected before Day 114 or after Day 122 post study vaccination.
- Visit 8 data collected before Day 165 or after Day 195 post study vaccination.
- Visit 9 data collected before Day 350 or after Day 401 post study vaccination.

For analyses using the PP population, subjects will be grouped based on study vaccinations received.

6.4. Covariates and Subgroups

This protocol defines a subgroup analysis to summarize HAI, NAI, and Neut antibody titers against vaccine strains by baseline seropositive status and previous vaccination by seasonal influenza vaccine as defined for stratification (Either 2017-2018 or 2018-2019, Neither 2017-2018 or 2018-2019). As this study is not adequately powered to perform subgroup analyses, these subgroup analyses will be used for exploratory purposes only.

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 such analysis will be reported and substantive differences will be described.

6.6. Interim Analyses and Data Monitoring

Interim analyses will only be used to terminate this trial in the event that unanticipated safety events deemed to be of sufficient concern require such action by the sponsor. These assessments will not be made on the basis of testing a formal statistical hypothesis; therefore, p-value adjustment will not be made to any analyses. A DSMB will be convened by DMID to review study progress and participant, clinical, safety, and reactogenicity and immunogenicity data.

An expedited report of safety data through Day 57 and HAI, NAI, and Neut data against 2018/2019 QIV strains and heterologous strains from baseline (Day 1) and Day 29 unblinded by study arm will be prepared in Section 6.2.1; though this report will be released while subjects remain in the trial for long-term safety and immunogenicity follow-up, it will be considered the final analysis of these data.

Emergent public health needs may dictate additional interim safety, reactogenicity, and/or immunogenicity analyses be performed on available information at any time during the trial. If this occurs, immunogenicity data will be analyzed as results are available from the central immunogenicity laboratory.

6.6.1. Interim Safety Review

An interim safety review may include enrollment and demographic information, medical history, concomitant medications, physical assessments, clinical laboratory values, dosing compliance, and solicited and unsolicited AE/SAEs. Additional data may be requested by the DSMB, and interim statistical reports may be generated as deemed necessary and appropriate by DMID. The DSMB may receive data in aggregate and presented by study arm, including expected and observed rates of the expected AEs. The DSMB will review

grouped data in the closed session only. The DSMB will meet and review this data at scheduled time points or ad hoc as needed during this trial as defined in the DSMB charter. As an outcome of each review/meeting, the DSMB will make a recommendation as to the advisability of proceeding with study vaccinations (as applicable), and to continue, modify, or terminate this trial.

Additionally, this trial will be monitored to determine if any of the halting rules described in Section 9.5 of the protocol are met.

6.6.2. Interim Immunogenicity Review

There is no plan to halt this trial prior to full enrollment and completion of all follow-up visits based on interim immunogenicity results. An Expedited Interim Immunogenicity Report of HAI, NAI, and Neut serum antibody responses will be generated as described in Section 6.2.

Immune responses will be summarized in terms of strain-specific 2018/2019 QIV HAI, NAI, and Neut antibody titers and the relationship to study arm. All analyses will be carried out in parallel for all assays and provided in the expedited report. Interim analyses will focus on rates of titers ≥1:40, seroconversion (see definition in Section 3.2), GMFRs, and GMTs, along with corresponding 95% confidence intervals. No formal hypothesis testing will be included in the interim analysis. All interim analyses will use the mITT population.

Tables to be included in in the Expedited Report are indicated with the symbol * in the title. These include Table 21, Table 22, Table 23, Table 24, Table 25, Table 26, Table 27, and Table 28 for HAI antibodies against 2018/2019 QIV strains; Table 29, Table 30, Table 31, Table 32, Table 33, Table 34, Table 35, and Table 36 for Neut antibodies against 2018/2019 QIV strains; Table 55, Table 56, Table 57, Table 58, Table 59, Table 60, Table 61, and Table 62 for NAI antibodies against 2018/2019 QIV strains presenting summaries and 95% CIs by study arm. Additionally, HAI, NAI, and Neut results against heterologous strains will be presented starting with Table 81 and ending with Table 110.

6.7. Multicenter Studies

Randomization was stratified by site, but data will be pooled across all clinical sites for all analyses. Center effects are not anticipated because the sites use standardized procedures for vaccination and assessment of solicited and unsolicited AEs, and the study relies on a central laboratory for immunogenicity assessments.

6.8. Multiple Comparisons/Multiplicity

This study was designed to obtain preliminary estimates of safety and immune response to 2018/2019 Fluzone and Flublok vaccines with or without AF03 or Advax-CpG55.2 adjuvants in healthy adults. The study was not designed to test any specific null hypothesis, and as such no adjustment for multiple comparisons will be performed.

7. STUDY SUBJECTS

7.1. Disposition of Subjects

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

The number and percentage of enrolled subjects excluded from each analysis population by study arm are presented in Table 12. A listing of subjects excluded from each analysis population will be presented in Listing 5.

The disposition of subjects in the study will be tabulated by study arm (Table 13). The table will show the total number of subjects screened, randomized, receiving the first study vaccination, receiving the second study vaccination, completing the blood draw for the primary immunogenicity endpoints, and completing the last visit.

A flowchart showing the disposition of study subjects, adapted from the CONSORT Statement [2] will be included and will present the number of subjects screened, randomized, lost to follow up, and analyzed, by study arm (Figure 1).

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

7.2. Protocol Deviations

A summary of subject-specific protocol deviations will be presented by the deviation category and deviation type, and study arm for all enrolled subjects (Table 6). Major deviations that will be reviewed for possible exclusion of immunogenicity results from the PP population including deviations related to eligibility/ enrollment, treatment administration schedule, follow-up visit schedule, and receipt of exclusionary vaccines or medications. All subject-specific protocol deviations and non-subject-specific protocol deviations will be included in Listing 3 and Listing 4.

8. IMMUNOGENICITY EVALUATION

Immunogenicity data summaries and analysis for primary and secondary endpoints will be presented for the mITT and PP populations. Immune responses in terms of strain-specific 2018/2019, 2019/2020 QIV HAI, NAI, and Neut antibody titers will be summarized by study arm at each time point. Descriptive summary statistics will be provided for all assays and time points including number of subjects with non-missing results, percentage of subjects with titers ≥1:40 for HAI and Neut only, percentage of subjects achieving seroconversion, GMTs along with corresponding 95% CI, and GMFRs along with corresponding 95% CI. Exact confidence intervals using the Clopper Pearson method will be presented for proportional endpoints. Ratios of GMTs along with their 95% CIs between adjuvanted and unadjuvanted groups will be presented at each timepoint. Confidence intervals using the Delta Method will be provided for the ratio of GMTs.

Individual HAI, NAI, and Neut assay results will be provided in Listing 9, Listing 10, and Listing 11. Individual exploratory assay results will be provided in Listing 12, Listing 13, and Listing 14 for memory B cells, Listing 15 for Tfh cells, Listing 16 for plasmablasts, Listing 17 for neutralizing fc-effector, Listing 18 for antibody forensics, and Listing 19 for NA ELISA.

8.1. Primary Immunogenicity Analysis

The primary immunogenicity endpoints HAI, Neut and NAI seroconversion, percentage of subjects with titer ≥1:40 for HAI and Neut only, GMTs, ratios of GMTs between adjuvanted and unadjuvanted groups, and GMFRs against the 2018/2019 QIV strains 28 days after study vaccination (Day 29) will be summarized as described above. The primary analysis population will be mITT, with results from the PP population providing a comparison of the sensitivity of immunogenicity results to subject adherence to protocol-defined conditions.

Summaries of primary immunogenicity endpoints are presented for the 2018/2019 QIV strains in Table 21, Table 22, Table 23, Table 24, Table 25, Table 26, Table 27, and Table 28 for HAI, Table 29, Table 30, Table 31, Table 32, Table 33, Table 34, Table 35, and Table 36 for Neut, and Table 53, Table 54, Table 55, Table 56, Table 57, Table 58, Table 59, and Table 60 for NAI.

8.2. Secondary Immunogenicity Analyses

The secondary immunogenicity endpoints HAI, Neut and NAI seroconversion, percentage of subjects with titer ≥ 1:40 for HAI, GMFRs, GMTs, and ratios of GMTs (between adjuvanted group and unadjuvanted) against the 2019/2020 QIV strains 28 days after vaccination with the 2019/2020 QIV (Day 118) will be summarized as described above. HAI and Neut seroconversion, percentage of subjects with HAI titers ≥ 1:40, GMFRs, GMTs, and ratios of GMTs for HAI and Neut against heterologous influenza A/H3 strains on approximately Days 8, 29, 57, 90, and 118 after study vaccination with the 2018/2019 QIV will be also presented. HAI, Neut and NAI seroconversion, percentage of subjects with HAI and Neut titers ≥1:40, and GMTs against the 2018/2019 QIV strains on approximately Days 8, 29, 57, 90, and 118 after study vaccination will be presented. HAI, Neut, and NAI GMFRs against the 2018/2019 QIV strains on approximately Day 57 and Day 90 will also be presented. NAI seroconversion, NAI GMTs and ratios of NAI GMTs against heterologous N1 and N2 NA antigens will also be assessed on approximately Days 8, 29, 57, 90, and 118 for study groups 1, 2 and 3. No formal hypothesis testing is planned.

Secondary summaries for the 2019/2020 QIV strains are provided in Table 69, Table 70, Table 71, Table 72, Table 73, Table 74, Table 75, Table 76, Table 77, Table 78, Table 79, and Table 80. Summaries of HAI, and Neut against heterologous H3 Influenza strains for both mITT and PP populations will also be provided in Table 81, Table 82, Table 83, Table 84, Table 85, Table 86, Table 87, Table 88, Table 89, and Table 90 for HAI, and Table 91, Table 92, Table 93, Table 94, Table 95, Table 96, Table 97, and Table 98 for Neut. Summaries of NAI against heterologous N1 and N2 antigens will be presented in Table 99, Table 100, Table 101, Table 102, Table 103, Table 104, Table 105, Table 106, Table 107, Table 108, Table 109, and Table 110.

Reverse cumulative distribution (RCD) curves will be presented for baseline and post-vaccination HAI, Neut and NAI antibody titers against 2018/2019 and 2019/2020 QIV strains, HAI and Neut antibody titers against heterologous influenza A/H3 strains, and NAI antibody titers against heterologous N1 and N2 NA antigens. Plots for titers HAI, Neut, and NAI titers against the 2018/2019 QIV strains will be generated with eight panels (Day 1 (Baseline), Day 8, Day 29, Day 57, Day 90, and Day 118), and separate curves within each panel for each study arm, as shown beginning with Figure 2, and ending with Figure 25. RCD curves for HAI, Neut, and NAI against the 2019/2020 QIV strains will be generated with four panels (Day 90 (Baseline) and Day 118) and be presented starting with Figure 26, and ending with Figure 49. In a similar manner, RCD curves of HAI titers against heterologous influenza A/H3 strains will be presented in Figure 50, Figure 51, Figure 52, Figure 53, Figure 54, Figure 55, Figure 56, Figure 57, Figure 58, and Figure 59, and those for Neut titers against heterologous influenza A/H3 strains in Figure 60, Figure 61, Figure 62, Figure 63, Figure 64, Figure 65, Figure 66, Figure 67, Figure 68, and Figure 69 for Neut. RCD curves of NAI titers against heterologous N1 and N2 NA antigens will be presented in Figure 70, Figure 71, Figure 72, Figure 73, Figure 74, Figure 75, Figure 76, Figure 77, Figure 78, Figure 79, Figure 80, and Figure 81.

Geometric Mean Titers of HAI, Neut, and HAI against 2018/2019 QIV strains by study day and study arm will be plotted in Figure 82, Figure 83, Figure 84, Figure 85, Figure 86, and Figure 87.

8.3. Exploratory Immunogenicity Analyses

The exploratory immunogenicity endpoints HAI, Neut and NAI seroconversion, percentage of subjects with titer ≥ 1:40 for HAI, GMFRs, GMTs, and ratios of GMTs (between adjuvanted group and unadjuvanted) against the 2019/2020 QIV strains 28 days after vaccination with the 2019/2020 QIV (Day 118) will be summarized as described above. HAI and Neut seroconversion, percentage of subjects with HAI titers ≥ 1:40, GMFRs, GMTs, and ratios of GMTs for HAI and Neut against heterologous influenza A/H3 strains on approximately Days 180 and 365 after study vaccination with the 2018/2019 QIV will be also presented. HAI, Neut and NAI seroconversion, percentage of subjects with HAI and Neut titers ≥1:40, and GMTs against the 2018/2019 QIV strains on approximately Days 180 and 365 after study vaccination will be presented. NAI seroconversion, NAI GMTs and ratios of NAI GMTs against heterologous N1 and N2 NA antigens will also be assessed on approximately Days 180 and 365 for study groups 1, 2 and 3. No formal hypothesis testing is planned.

Summaries of HAI, and Neut against heterologous H3 Influenza strains for both mITT and PP populations for Days 180 and 365 will also be provided in Table 81, Table 82, Table 83, Table 84, Table 85, Table 86, Table 87, Table 88, Table 89, and Table 90 for HAI, and Table 91, Table 92, Table 93, Table 94, Table 95, Table 96, Table 97, and Table 98 for Neut. Summaries of NAI against heterologous N1 and N2 antigens for Days 180 and 365 will be presented in Table 99, Table 100, Table 101, Table 102, Table 103, Table 104, Table 105, Table 106, Table 107, Table 108, Table 109, and Table 110.

Reverse cumulative distribution (RCD) curves will be presented for baseline, Day 180, and Day 365 HAI, Neut and NAI antibody titers against 2018/2019 and 2019/2020 QIV strains, HAI and Neut antibody titers against heterologous influenza A/H3 strains, and NAI antibody titers against heterologous N1 and N2 NA antigens. Two panels will be added to figures described in Section 8.2 to add Day 180 and Day 365 timepoints.

Immunogenicity data summaries and analysis for the following exploratory endpoints will be presented for the PP populations. Immunogenicity results from the subgroup analysis by baseline serostatus for 2018/2019 QIV strains will be presented in Table 37, Table 38, Table 39, and Table 40 for HAI, Table 41, Table 42, Table 43, and Table 44 for Neut, and Table 61, Table 62, Table 63, and Table 64 for NAI. Similarly, subgroup results by previous vaccination will be presented in Table 45, Table 46, Table 47, and Table 48 for HAI, Table 49, Table 50, Table 51, and Table 52 for Neut, and Table 65, Table 66, Table 67 and Table 68 for NAI. Subgroup analysis results for HAI, Neut, and NAI against 2019/2020 QIV strains are presented in Table 71,Table 72, Table 75, Table 76, Table 79, and Table 80. Summary statistics for influenza specific IgG, IgM, and IgA B memory cells will be presented in Table 111, Table 112, and Table 113. Summary statistics including the mean, GM, and mean absolute difference for influenza specific plasmablasts and Tfh cells will be presented in Table 114, and Table 115, respectively. GMT and GMFRs of functioning non-neutralizing Fc-effector antibodies Against 2018/2019 QIV Strains will be provided in Table 116.

Plots for HA and NA binding antibodies against different H3 strains will be presented in Figure 88 and Figure 89.

Association of non-neutralizing Fc-effector antibody titers and HAI antibody titers, HAI seroconversion, and HAI seroprotection against 2018/2019 QIV strains are presented in Figure 90, Figure 92, and Figure 94. Similar plots are generated for the association of non-neutralizing Fc-effector antibody titers and Neut antibody titers, Neut seroconversion, and Neut seroprotection against 2018/2019 QIV strains and presented in Figure 91, Figure 93, and Figure 95.

9. SAFETY EVALUATION

All summaries and analysis of safety data will be presented for the Safety Analysis Population. Safety summaries will be presented overall and grouped by study arm.

Continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. All categorical measures will be summarized by the frequency and percentages of observed levels will be reported for all categorical measures. The denominator for the percentages may be based on the number of non-missing observations for an assessment or based on the number of subjects in a population. This will be described for each table.

9.1. Demographic and Other Baseline Characteristics

Summaries of age, sex, ethnicity, race, BMI, and prior receipt of seasonal influenza vaccine will be presented by site (Table 16, Table 17) and by study arm (Table 18, Table 19). Age will be summarized as a continuous variable. Ethnicity is categorized as Hispanic or Latino, or not Hispanic and not Latino. In accordance with NIH reporting policy, subjects may self-designate as belonging to more than one race or may refuse to identify a race, the latter reflected in the electronic case report form (eCRF) as "No" to each racial option. BMI will be summarized as a continuous as well as categorical variable, categorized as (<30, ≥30). Self-reported history of prior receipt of seasonal influenza vaccine will be categorized as follows: Either 2017-2018 or 2018-2019, Neither 2017-2018 or 2018-2019, or unknown. Demographic information for individual subjects will be provided in Listing 6. Subjects' prior influenza vaccination history (seasonal and non-seasonal) will be provided in Listing 8.

9.1.1. Prior and Concurrent Medical Conditions

All current illnesses and past or pre-existing medical conditions will be coded using Medical Dictionary for Regulatory Activities (MedDRA®) version 20.0 or higher.

Summaries of subjects' prior and concurrent medical conditions will be presented by study arm (Table 20).

Individual subject listings will be presented for all reported medical history including prior and concurrent medical conditions (Listing 7).

9.1.2. Prior and Concomitant Medications

Concomitant medications will be coded to the Anatomical Therapeutic Classification using the WHO Drug Dictionary. The use of concomitant medications during the study will be summarized by ATC1 and ATC2 code and study arm for the Safety Population (Table 169). A listing of concomitant medications will be presented (Listing 27).

9.2. Measurements of Treatment Compliance

All subjects are to receive 2 study vaccinations administered in the clinic. The number of subjects receiving study vaccination by month will be presented by study arm and by site in Table 14 and Table 15 and as part of the subject disposition table (Table 13). Listing 1 presents subjects who received investigational product with randomized study arm and study product received for each study vaccination.

9.3. Adverse Events

A summary of all adverse events is provided in Table 117. A summary of those events that occurred in ≥5% of subjects in any study arm is provided in Table 118.

9.3.1. Solicited Events and Symptoms

Systemic solicited adverse events were collected pre-vaccination, and systemic and local solicited adverse events were collected at-least 20 minutes post-vaccination and then daily for 7 days after the first study vaccination and graded on a scale of 0 (none), 1 (mild), 2 (moderate) and 3 (severe). Systemic events include fever, feverishness, fatigue, malaise, myalgia, arthralgia, headache, and nausea. Local events include pruritus, ecchymosis, erythema, induration/swelling, pain, and tenderness. Ecchymosis, erythema, and induration are measured by both functional and measurement grading scales as defined in Table 7. The grading scale for systemic events, including quantitative grading for fever, is included in Table 8.

When calculating the incidence of solicited events, each subject will be counted once at the highest severity following the applicable vaccination, and any repetitions will be ignored. For summaries presented for the first study vaccination, the denominator for percentages will be the number of subjects who received the first study vaccination with non-missing data for the event summarized.

The number and percentage of subjects reporting at least one solicited adverse event of each severity will be summarized for each solicited symptom, any systemic symptom, any local symptom, and any symptoms. For each event the denominator is the number of subjects who received the first study vaccination with non-missing data for the specific event. The 95% CI calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option) will be presented (Table 119). Logistic regression models will be fit to estimate the effect of study arm on the probability of reporting any local event or reporting any systemic event (Table 120, Table 121). If statistically significant effects are observed in the model for local events or systemic events, then additional models may be fit for each individual event of that type.

$$logit[P(Event)] = \beta_0 + \beta_1 \times Treatment + \varepsilon,$$

For each systemic and local event, any systemic event, any local event, and any solicited event, the maximum severity over 7 days after the first study vaccination will be summarized for the Safety Population. The number and percentage of subjects reporting each event will be summarized by the maximum severity and study arm. For each event the denominator is the number of subjects who received the first study vaccination with non-missing data for the specific event. The 95% CI calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option) will be presented (Table 122).

The number of subjects reporting a solicited adverse event will be summarized for each day post the first study vaccination combined both in a summary table (Table 123) and graphically in a bar chart (Figure 96 and Figure 97).

Systemic and Local solicited events reported by subject will be presented in Listing 20 and Listing 21, sorted by subject ID, vaccination number, parameter, and study day.

9.3.2. Unsolicited Adverse Events

When calculating the incidence of unsolicited AEs (i.e., on a per subject basis), each subject will only be counted once at the highest severity and/or relationship, and any repetitions of AEs within a subject will be

ignored; the denominator will be the total number of subjects in the safety population. All AEs reported will be included in the summaries and analyses.

A summary of all unsolicited adverse events by MedDRA SOC, PT, and study arm that occurred from Day 1 to Day 365 is provided in Table 124. Similarly, a summary of all unsolicited adverse events by MedDRA SOC, PT, and study arm that occurred from Day 1 to Day 29 is provided in Table 125.

The number and percentage of subjects reporting at least one unsolicited AE will be summarized by MedDRA system organ class and preferred term. A 95% CI will be presented for the percentage of subjects reporting any unsolicited AE (serious or non-serious) for each MedDRA system organ class and preferred term over all study vaccinations (Table 126). A similar table summarizing all unsolicited events from Day 1 to Day 29 will be provided (Table 127).

The following summaries for unsolicited AEs will be presented by MedDRA system organ class, preferred term, and study arm:

- Incidence of AEs by severity and relationship to study product (Table 128);
- Incidence of AEs from Day 1 to Day 29 by severity and relationship to study product (Table 129);
- Incidence of non-serious, related AEs by severity (Table 130);
- Incidence of AEs over time (Days 1-8, Days 9-29 post first study vaccination) (Table 131);
- Incidence of non-serious, related AEs over time (Days 1-8, Days 9-29 post first study vaccination) (Table 132)
- Total frequency of AEs over time (Days 1-8, Days 9-29 post first study vaccination) (Table 133);
- Subject listing of non-serious AEs of moderate or greater severity (Table 138);
- Bar chart displaying total frequency of AEs by severity and MedDRA system organ class and study arm (Figure 98);
- Bar chart displaying incidence of AEs by severity and MedDRA system organ class, and study arm (Figure 99);
- Bar chart displaying total frequency and incidence of AEs by relationship to study product, MedDRA system organ class, and study arm (Figure 100 and Figure 101).

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

The following listings will be presented including Subject ID, Age (years) AE Description, AE Onset Date/End Date, Last Vaccination Received/Days Post Vaccination, Reason Reported as an SAE, Relationship to Study Product, Alternate Etiology if not Related, Outcome, and Duration of Event (days):

- Deaths and Serious Adverse Events (Table 134);
- Adverse Events of Special Interest (Table 135);
- Potentially Immune Mediated Medical Conditions (Table 136);

- New Onset Chronic Medical Conditions (Table 137).

A listing of all reported AEs by subject will be presented in Listing 22, sorted by Study Arm, Subject ID, and AE Number.

9.5. Pregnancies

For any subjects in the Safety Population who became pregnant during the study, every attempt will be made to follow these subjects to completion of pregnancy to document the outcome, including information regarding any complications with pregnancy and/or delivery.

Listing 28, Listing 29, Listing 30, Listing 31, and Listing 32 will present any study pregnancies and their outcomes.

9.6. Clinical Laboratory Evaluations

Clinical safety laboratory parameters (WBC, Hgb, PLT, ALT, AST, T. Bili, GGT, ALP, Amylase, Lipase, Cr) will be collected from each subject prior to the first study vaccination and approximately 7 days the first study vaccination. These evaluations will be performed by the central clinical laboratory. The grading scale for clinical laboratory evaluations is presented in Table 10. Clinical laboratory evaluations assessed on Day 1 prior to the first study vaccination will be considered as baseline.

The distribution of laboratory results by severity, study day and study arm will be presented starting with Table 139 and ending with Table 150. Descriptive statistics including mean, standard deviation, median, minimum and maximum values and change from baseline by study day will be summarized for each parameter starting with Table 151 and ending with Table 161. Box plots illustrating the change from baseline for each laboratory parameter will be presented starting with Figure 102 and ending with Figure 112. Subject visits with abnormal laboratory results, Grade 1 severity or higher, will be presented in Table 162 and Table 163 for Chemistry and Hematology parameters, respectively.

A complete listing of individual clinical laboratory results will be presented in Listing 23 and Listing 24 for chemistry and hematology, respectively, sorted by subject ID, parameter, and visit number.

9.7. Vital Signs and Physical Evaluations

Vital signs oral temperature, systolic blood pressure, diastolic blood pressure, and pulse will be assessed prior to study vaccination on Day 1. The grading scale for vital sign evaluations is presented in Table 9. Summaries of vital signs by maximum severity will be tabulated by visit, and study arm (Table 164, Table 165, Table 166 , Table 167, Table 168). A listing of vital signs will be presented (Listing 25).

Targeted physical examinations will be performed, if indicated, based a subject's medical history. A listing of physical exam findings will be presented (Listing 26).

9.8. Concomitant Medications

Concomitant medications will be collected for the 30 days prior to the first study vaccination through 28 days after the first study vaccination. Concomitant medications will be coded to the Anatomical Therapeutic Classification using the WHO Drug Dictionary. The use of prior and concomitant medications taken during the study will be recorded on the CRFs. A by-subject listing of concomitant medication use will be presented

(Listing 27). The use of concomitant medications during the study will be summarized by ATC1, ATC2 code, and study arm for the Safety Population (Table 169).

10. REPORTING CONVENTIONS

P-values ≥0.001 and ≤0.999 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001"; p-values greater than 0.999 will be reported as "> 0.999". The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Proportions will be presented as two decimal places; values <0.01 will be presented as "<0.01". Percentages will be reported to the nearest whole number; non-zero values < 1% will be presented as "<1"; values greater than 99% but less than 100% will be presented as >99. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

11. TECHNICAL DETAILS

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

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

This SAP includes one change from the analyses described in the protocol. Logistic regression will be used instead of the Chi-Square or Fisher's exact test to model the relationship of treatment with reporting any local or systemic events post vaccination. Besides providing the strength of the association between the treatment and probability of reporting any local or systemic event in terms of odds ratio, logistic regression also provides a prediction model for the probability of a local or solicited event occurring given the subject's study arm. Version 3.0 of the SAP includes moving Day 180 and Day 365 immunogenicity endpoints from secondary to exploratory endpoints and the addition of a topline report.

13. REFERENCES

1. FDA Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines (US DHHS, FDA, CBER, May 2007).
2. Drummond R. CONSORT Revised: Improving the Reporting of Randomized Clinical Trials. JAMA. 2001; 285(15):2006-2007.

14. LISTING OF TABLES, FIGURES, AND LISTINGS

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

APPENDICES

APPENDIX 1. TABLE MOCK-UPS

LIST OF TABLES

9.1 Overall Study Design and Plan Description

Table 1: Study Design

		Day 1		Day 90
Study Group	**N**	**Study Vaccine**	**Adjuvant**	**Seasonal Vaccine**
1	**40**	**Fluzone 2018/2019 QIV**	None	Fluzone 2019/2020 QIV
2	**40**	**Fluzone 2018/2019 QIV**	AF03	Fluzone 2019/2020 QIV
3[A]	**40**	**Fluzone 2018/2019 QIV**	Advax-CpG55.2	Fluzone 2019/2020 QIV
4	**40**	**Flublok 2018/2019 QIV**	None	Flublok 2019/2020 QIV
5	**40**	**Flublok 2018/2019 QIV**	AF03	Flublok 2019/2020 QIV
6[A]	**40**	**Flublok 2018/2019 QIV**	Advax-CpG55.2	Flublok 2019/2020 QIV
	Total N= 240			

Note: Cohorts will be enrolled simultaneously. Randomization at each site will be stratified by prior receipt of licensed, seasonal influenza vaccine (defined as receipt of at least one of the 2017/2018 and/or 2018/2019 licensed, seasonal influenza vaccines).

9.5.1 Efficacy/Immunogenicity and Safety Measurements Assessed and Flow Chart

Table 2: Schedule of Study Procedures and Evaluations

Study Visit Number	**V00**	**V01**	**V02**	**V03**	**V04**	**V05**	**V06**	**V07**	**V08**	**V09**	**Early Termination**	**Unscheduled**
Screening, Enrollment/Study Day and post first study vaccination	**Screening D-28 to -1**	**Enrollment D1**	**D2+1d**	**D8+/-1d**	**D29+/-2d**	**D57+/-3d**	**D90+/-14d**	**Day118+/-3d**	**D180 +/-14d**	**D365 +/-14d**		
Informed Consent[∞]	X[∞]											
Demographic Information	X											
Eligibility Criteria	X	X[†¬1]										
Medical History[@]	X	X[†¬]	X	X	X	X	X	X	X	X	X	X
Concomitant Medications	X	X[†¬]	X	X	X						X[6]	X[6]
Vital Signs (Oral Temperature[%], Pulse and BP)	X	X[$]									X	X
Height and Weight	X											
Physical Examination	X[2]	{X}	{X}	{X}	{X}	{X}	{X}[†]	{X}	{X}	{X}	{X}	{X}
Urine or Serum Pregnancy Test	X[^]	X[†^]										
Venous Blood Collection for Screening Laboratories	X[≠]											
Enrollment in Advantage eClinical[SM] and Randomization		X[†]										
Venous Blood Collection for Clinical Safety Laboratory Evaluations~		X[†,~]		X[~]							X[7]	X
Venous Blood Collection for Serological Assays		X[†]		X	X	X	X[†]	X	X	X	X	X
Venous Blood Collection for Cellular Immunology Assays		X[†]		X	X		X[†]				X[8]	
Venous Blood Collection for Transcriptomics		X[†]	X	X							X[9]	
Pre-Administration Reactogenicity Assessments		X[†]										
Study Vaccination		X					X[*]					
20-minute Evaluation After Study Vaccination		X										
Examine Study Vaccination Site		X	X	X							X[7]	X[7]
Post-Administration Reactogenicity Assessments		X									X[7]	X[7]
Distribute Memory Aid and Study-Related Materials		X										

Study Visit Number	**V00**	**V01**	**V02**	**V03**	**V04**	**V05**	**V06**	**V07**	**V08**	**V09**	**Early Termination**	**Unscheduled**
Screening, Enrollment/Study Day and post first study vaccination	**Screening D-28 to -1**	**Enrollment D1**	**D2+1d**	**D8+/-1d**	**D29+/-2d**	**D57+/-3d**	**D90+/-14d**	**Day118+/-3d**	**D180 +/-14d**	**D365 +/-14d**		
Review Memory Aid			X	X							X[7]	X[7]
AE/SAE Assessment		X[&,3]	X[&,3]	X[&,3]	X[3]	X	X[4]	X[4]	X[4]	X[4]	X[3,6]	X[3,6]

∞ Prior to study procedures.
¬ Review/confirm information or activity in subjects previously consented and screened.
† Prior to study vaccination.
1 Review results of ESR and clinical safety laboratory evaluations.
@ Complete medical history (including solicitation for receipt of any non-study influenza vaccine) will be obtained by interview of subjects at the screening visit and interim medical history will be obtained by interview of subjects on Day 1 prior to study vaccination and at follow-up visits after study vaccination.
$ Vital signs assessed on Day 1 prior to the study vaccination will be considered as baseline.
% Subjects must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.
2 At the screening visit a physical examination will be performed on all subjects to include the following organs and organ systems: skin, head and neck, lungs, heart, liver, spleen, extremities, lymph nodes, and nervous system.
{} Targeted physical examination if indicated based on review of interim medical history.
^ Performed locally by the site at the screening visit (optional); Must be performed within 24 hours prior to study vaccination for all women of childbearing potential. Results must be negative and known prior to randomization on Day 1 and administration of study vaccination.
≠ ESR Performed by local laboratory, WBC, Hgb, PLT, ALT, T. Bili, AST, GGT, ALP, serum lipase, serum amylase and Cr will be sent to the central clinical laboratory.
~ Includes, WBC, Hgb, PLT, ALT, T. Bili, AST, GGT, ALP, serum lipase, serum amylase and Cr.
& Inclusive of reactogenicity assessments performed on the day of study vaccination through 7 days after study vaccination.
3 AEs (if visit occurs on or before Day 29), SAEs, AESIs (including Protocol Specified AESIs, MAAEs, NOCMCs and PIMMCs), for subjects who are being followed for safety.
4 SAEs and AESIs (including Protocol Specified AESIs, MAAEs, NOCMCs and PIMMCs), for subjects who are being followed for safety.
5 Investigators have the discretion of administering 2019/2020 Fluzone or Flublok earlier than the Day 90 window (i.e. earlier than Day 76) if 10% of more of surveillance samples in the CDC geographic region surrounding the local site test positive for influenza.
6 If within 365 after first study vaccination
7 If within the first 7 days after the first study vaccination
8 If prior to or at the D90 visit
9 If prior to or at the D8 visit
* Seasonal QIV 2019/2020

9.7.1 Sample Size

Table 3: Probability (%) to Detect Safety Events

Event Frequency	N = 4	N = 6	N = 40	N = 60	N = 120	N = 240
≥10% Very Common	34	46	98	>99	>99	>99
≥1% Common	3	5	33	45	70	91
≥0.1% Uncommon	<1	<1	3	5	11	21
≥0.01% Rare	<1	<1	<1	<1	1	2

Table 4: Precision of Binomial Confidence Intervals

N	95% CI
4	6-94
6	11-89
40	33 -67
60	36-64
120	40-60
240	43-57

Table 5: Minimum Detectable Difference in Proportion Responders with 80% Power

Assumed Proportion of subjects with titer ≥ 40 in comparator arm (p_c)	Minimum detectable difference in response rate (p_c-p_e), N=38 per group	Minimum detectable difference in response rate (p_c-p_e), N=58 per group
0.40	0.32	0.26
0.50	0.30	0.25
0.60	0.28	0.23
0.70	0.24	0.20
0.80	0.18	0.16
0.90	0.10	0.10

10.2 Protocol Deviations

Table 6: Distribution of Protocol Deviations by Category, Type, and Study Arm

Category	Deviation Type	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
Eligibility/enrollment	Any type														
	Did not meet inclusion criterion	x	x	x	x	x	x	x	x	x	x	x	x		
	Met exclusion criterion														
	ICF not signed prior to study procedures														
	Other														
Treatment administration schedule	Any type														
	Out of window visit														
	Missed visit/visit not conducted														
	Missed treatment administration														
	Delayed treatment administration														
	Other														
Follow-up visit schedule	Any type														
	Out of window visit														
	Missed visit/visit not conducted														
	Other														

Category	Deviation Type	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
Protocol procedure/assessment	Any type														
	Incorrect version of ICF signed														
	Blood not collected														
	Urine not collected														
	Stool not collected														
	Other specimen not collected														
	Too few aliquots obtained														
	Specimen result not obtained														
	Required procedure not conducted														
	Required procedure done incorrectly														
	Study product temperature excursion														
	Specimen temperature excursion														
	Other														
Treatment administration	Any type														
	Required procedure done incorrectly														
	Study product temperature excursion														

Category	Deviation Type	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
	Other														
Blinding policy/procedure	Any type														
	Treatment unblinded														
	Other														
N = Number of subjects enrolled.															

12.2.2 Displays of Adverse Events

Table 7: Solicited Adverse Event Grading Scale - Local

Local (Injection Site) Reactogenicity Grading			
Injection Site Reaction	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Pain – experienced without touching the injection site (spontaneous discomfort)	Subject 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	Subject is aware of pain; there is interference with daily activity **or** OTC pain medication is used for more than 24 hours	Subject is aware of pain, **and** it prevents daily activity or pain requires prescription medication
Tenderness-experienced with touching the injection site	Subject 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	Subject is aware of pain; there is interference with daily activity **or** OTC pain medication is used for more than 24 hours	Subject is aware of pain, **and** it prevents daily activity or pain requires prescription medication
Pruritus	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity or requires prescription medication
Ecchymosis (Bruising)*	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Erythema (Redness)*	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Induration (Hardness)/Edema (Swelling)*	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
Local (Injection Site) Reactogenicity Measurements			
Injection Site Reaction	**Small**	**Medium**	**Large**
Ecchymosis (Bruising)*	<20 mm	20 mm – 50 mm	>50 mm
Erythema (Redness)*	<20 mm	20 mm – 50 mm	>50 mm
Induration (Hardness)/Edema (Swelling)*	<20 mm	20 mm – 50 mm	>50 mm

Local (Injection Site) Reactogenicity Grading			
Injection Site Reaction	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
*Will also be measured in mm but size will not be used as halting criteria.			

Table 8: Solicited Adverse Event Grading Scale – Systemic

Subjective Systemic Reactogenicity Grading			
Systemic (Subjective)	**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*	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Arthralgia*	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
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
Quantitative Systemic (Oral Temperature) Reactogenicity Grading			
Systemic (Quantitative)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Fever[#] – oral[†]	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
* Not at injection site.			
[#] Oral temperature assessed on Day 1 prior to the first study vaccination will be considered as baseline.			
* A fever can be considered not related to the study product if an alternative etiology can be documented.			

Subjective Systemic Reactogenicity Grading			
Systemic (Subjective)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
†Subjects must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.			

Table 9: Vital Signs Adverse Event Grading Scale

Physiologic Parameter	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Bradycardia – beats per minute	45 – 46	40 – 44	<40
Tachycardia – beats per minute	101 – 130	131 – 155	>155
Hypotension (systolic) mmHg	80 – 84	75 – 79	<75
Hypotension (diastolic) mmHg	50 – 54	45 – 49	<45
Hypertension (systolic) mmHg	141 – 155	156 – 160	>160
Hypertension (diastolic) mmHg	91 – 100	101 – 110	>110
[#] Pulse and blood pressure assessed on Day 1 prior to the first study vaccination will be considered as baseline.			

12.4.1 Individual Laboratory Measurements and Abnormal Laboratory Values

Table 10: Laboratory Adverse Event Grading Scale

Hematology	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
WBC $10^3/\mu L$ (Decrease)	2.50 – 3.90	1.50 – 2.49	<1.50
WBC $10^3/\mu L$ (Increase)	10.60 – 15.00	15.01 – 20.00	>20.00
Hgb g/dL (Decrease) (Female)	10.1 – 11.4	8.5 – 10	<8.5
Hgb g/dL (Decrease) (Male)	11.0 – 12.4	9.5 – 10.9	<9.5
Platelets $10^3/\mu L$ (Decrease) EDTA	125 – 139	100 – 124	<100
Platelets $10^3/\mu L$ (Increase) EDTA	416 – 550	551– 750	>750
Platelets K/cu mm (Decrease) Citrate	115-124	100-114	<100
Platelets K/cu mm (Increase) Citrate	376-550	551-750	>750
Chemistry	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
ALT IU/L (Increase) (Female)	44 – 100	101 – 200	>200
ALT IU/L (Increase) (Male)	61 – 138	139 – 275	>275
Aspartate Amino Transferase IU/L (Increase) (Female)	37-90	91-180	> 180
Aspartate Amino Transferase IU/L (Increase) (Male)	44-108	109-215	> 215
Total Bilirubin mg/dL (Increase) – when accompanied by any increase in ALT	1.30 – 1.59	1.60 – 1.80	> 1.80
Total Bilirubin mg/dL (Increase) – when ALT is normal	1.30 – 1.89	1.90 – 2.40	> 2.40
Gamma-Glutamyl Transferase IU/L (Increase) (Female)	33-80	81-160	> 160
Gamma-Glutamyl Transferase IU/L (Increase) (Male)	50-123	124-245	> 245
Alkaline Phosphatase IU/L (Increase) (Female)	116-230	231-345	> 345
Alkaline Phosphatase IU/L (Increase) (Male)	116-230	231-345	> 345
Serum Amylase	122-182	183-242	>243
Serum Lipase	61-90	91-180	> 181
Creatinine mg/dL (Increase) (Female)	1.1 – 1.7	1.8 – 2.0	> 2.0
Creatinine mg/dL (Increase) (Male)	1.4 – 1.7	1.8 – 2.0	> 2.0

14.1 Description of Study Subjects

14.1.1 Disposition of Subjects

Table 11: Ineligibility Summary of Screen Failures

Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	n[a]	%[b]
Inclusion and Exclusion	Number of subjects failing any eligibility criterion	x	100
Inclusion	Any inclusion criterion	x	x
	[inclusion criterion 1]	x	x
	[inclusion criterion 2]	x	x
	[inclusion criterion 3]	x	x
Exclusion	Any exclusion criterion	x	x
	[exclusion criterion 1]	x	x
	[exclusion criterion 2]	x	x
	[exclusion criterion 3]	x	x

[a]More than one criterion may be marked per subject.

[b]Denominator for percentages is the total number of screen failures.

Table 12: Exclusions from Analysis Populations by Study Arm – All Enrolled Subjects*

[Implementation Note: Generate this table for the expedited report and only include Safety Population, modified Intent to Treat and Per Protocol, Day 29).]

Analysis Populations	Reason Subjects Excluded	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
Safety Population	Any Reason	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Study Dose 1 Not Received														
Modified Intent to Treat	Any Reason														
	Study Dose 1 Not Received														
	No Baseline Results Available														
	No Post-Vaccination Results Available														
Per-Protocol, All Visits	Found to be Ineligible At Baseline														
Per Protocol, Day 8	Any Reason														
	Study Vaccination 1 Not Received														
	No Baseline Results Available														
	No Day 8 Result Reported by Lab														
	Lost to Follow-up Before Day 8														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 8 Visit Out of Window														
Per Protocol, Day 29	Any Reason														

Analysis Populations	Reason Subjects Excluded	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Study Vaccination 1 Not Received														
	No Baseline Results Available														
	No Day 29 Result Reported by Lab														
	Lost to Follow-up Before Day 29														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 29 Visit Out of Window														
Per Protocol, Day 57	Any Reason														
	Study Vaccination 1 Not Received														
	No Baseline Results Available														
	No Day 57 Result Reported by Lab														
	Lost to Follow-up Before Day 57														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 57 Visit Out of Window														
Per Protocol, Day 90	Any Reason														
	Study Vaccination 1 Not Received														

Analysis Populations	Reason Subjects Excluded	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
	No Baseline Results Available														
	No Day 90 Result Reported by Lab														
	Lost to Follow-up Before Day 90														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 90 Visit Out of Window														
Per Protocol, Day 118	Any Reason														
	Study Vaccination 1 Not Received														
	No Baseline Results Available														
	No Day 118 Result Reported by Lab														
	Lost to Follow-up Before Day 118														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 118 Visit Out of Window														
Per Protocol, Day 180	Any Reason														
	Study Vaccination 1 Not Received														
	No Baseline Results Available														

Analysis Populations	Reason Subjects Excluded	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%
	No Day 180 Result Reported by Lab														
	Lost to Follow-up Before Day 180														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 180 Visit Out of Window														
Per Protocol, Day 365	Any Reason														
	Study Vaccination 1 Not Received														
	No Baseline Results Available														
	No Day 365 Result Reported by Lab														
	Lost to Follow-up Before Day 365														
	Receipt of Non-Study Vaccination														
	Receipt of Immunosuppressive medication														
	Day 365 Visit Out of Window														

N = Number of subjects enrolled.

Table 13: Subject Disposition by Study Arm, All Enrolled Subjects*

Subject Disposition	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Screened	x	--	x	--	x	--	x	--	x	--	x	--	x	--
Enrolled/Randomized	x	100	x	100	x	100	x	100	x	100	x	100	x	100
Received Vaccination 1	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Received Vaccination 2	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Primary Follow-up (Day 29)[a]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Blood Draw for Primary Immunogenicity Analysis (Day 29)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Included in Per Protocol Primary Immunogenicity Analysis (Day 29)[b]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Day 57 Visit	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Completed Final Study Visit (Day 365)	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

N = Number of subjects enrolled.
[a]Refer to Listing 2 for reasons subjects discontinued from study vaccinations or terminated early.
[b]Refer to Listing 5 for reasons subjects are excluded from the per protocol population.

Table 14: Dates of First Study Vaccination by Site and Study Arm for the Safety Analysis Population

[Implementation Note: The dates of dosing will be categorized by month.]

Dates of Dosing	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)	All Subjects (N=X)
[Site 1]							
Total (Entire period of enrollment)	x	x	x	x	x	x	x
17JUN2019-30JUN2019	x	x	x	x	x	x	x
01JUL2019-31JUL2019	x	x	x	x	x	x	x
01AUG2019-27AUG2019	x	x	x	x	x	x	x
[Site 2]							
Total (Entire period of enrollment)	x	x	x	x	x	x	x
17JUN2019-30JUN2019	x	x	x	x	x	x	x
01JUL2019-31JUL2019	x	x	x	x	x	x	x
01AUG2019-27AUG2019	x	x	x	x	x	x	x
[Repeat for all sites]							
N = Number of subjects in the Safety Population.							

Table with similar format

Table 15: Dates of Second Study Vaccination by Site and Study Arm for the Safety Analysis Population

[Implementation Note: Update the table to use actual dates of administration of the second vaccination grouped by month.]

14.1.2 Demographic Data

Table 16: Summary of Categorical Demographic and Baseline Characteristics by Site, All Enrolled Subjects

Variable	Characteristic	[Site 1] (N=X)		[Site 2] (N=X)		[Site 3] (N=X)		[Site 4] (N=X)		[Site 5] (N=X)		[Site 6] (N=X)		[Site 7] (N=X)		[Site 8] (N=X)		[Site 9] (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sex	Male	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Female																				
BMI	< 30																				
	≥ 30																				
	Unknown																				
Ethnicity	Not Hispanic or Latino	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Hispanic or Latino																				
	Not Reported																				
	Unknown																				
Race	American Indian or Alaska Native	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Asian																				
	Native Hawaiian or Other Pacific Islander																				
	Black or African American																				
	White																				
	Multi-Racial																				
	Unknown																				
Prior Seasonal Influenza Vaccination	Either 2017-2018 or 2018-2019																				
	Neither 2017-2018 or 2018-2019																				

N= Number of subjects enrolled.

Table 17: Summary of Continuous Demographic and Baseline Characteristics by Site, All Enrolled Subjects

Variable	Statistic	[Site 1] (N=X)	[Site 2] (N=X)	[Site 3] (N=X)	[Site 4] (N=X)	[Site 5] (N=X)	[Site 6] (N=X)	[Site 7] (N=X)	[Site 8] (N=X)	[Site 9] (N=X)	All Subjects (N=X)
Age	Mean	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Standard Deviation	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Minimum	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x
BMI	Mean	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Standard Deviation	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Minimum	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x

N= Number of subjects enrolled.

Table 18: Summary of Categorical Demographic and Baseline Characteristics by Study Arm, All Enrolled Subjects*

Variable	Characteristic	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (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														
BMI	< 30														
	≥ 30														
Ethnicity	Not Hispanic or Latino	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Hispanic or Latino														
	Not Reported														
	Unknown														
Race	American Indian or Alaska Native	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Asian														
	Native Hawaiian or Other Pacific Islander														
	Black or African American														
	White														
	Multi-Racial														
	Unknown														
Prior Seasonal Influenza Vaccination	Either 2017-2018 or 2018-2019														
	Neither 2017-2018 or 2018-2019														

N= Number of subjects enrolled.

Table 19: Summary of Continuous Demographic and Baseline Characteristics by Study Arm, All Enrolled Subjects*

Variable	Statistic	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)	All Subjects (N=X)
Age	Mean	xx	xx	xx	xx	xx	xx	xx
	Standard Deviation	xx	xx	xx	xx	xx	xx	xx
	Median	xx	xx	xx	xx	xx	xx	xx
	Minimum	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x
BMI	Mean	xx	xx	xx	xx	xx	xx	xx
	Standard Deviation	xx	xx	xx	xx	xx	xx	xx
	Median	xx	xx	xx	xx	xx	xx	xx
	Minimum	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x

N= Number of subjects enrolled.

14.1.3 Prior and Concurrent Medical Conditions

Table 20: Summary of Subjects with Prior or Concurrent Medical Conditions by MedDRA System Organ Class and Study Arm, Safety Analysis Population

MedDRA System Organ Class	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
	n	%	n	%	n	%								
Any SOC	x	xx	x	xx	x	xx								
[SOC 1]														
[SOC 2]														
…														

Note: N = Number of subjects in the Safety Population.
n = Number of subjects reporting medical history within the specified SOC. A subject is only counted once per SOC.

14.2 Efficacy/Immunogenicity Data

Table 21: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

[Implementation Note: This table will be generated for the expedited report to include only results for Day 1 and Day 29]

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Titer < 10 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 8 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xxx.x,xxx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
GMFR (95% CI)	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)
Day 57 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 90 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 180 Post Vaccination 1						
n	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 365 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Tables with similar format

Table 22: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 23: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 24: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 25: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Per Protocol Population*¥

Table 26: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Per Protocol Population*¥

Table 27: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population*¥

Table 28: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population*¥

Table 29: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 30: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 31: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 32: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 33: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Per Protocol Population*¥

Table 34: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Per Protocol Population*¥

Table 35: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 36: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 37: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 1 (Pre-Vaccination 1)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Titer < 10 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 8 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Day 29 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 57 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 90 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 180 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 365 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Tables with similar format

Table 38: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 39: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 40: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 41: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 42: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 43: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 44: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 45: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]
Day 1 (Pre-Vaccination 1)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Titer < 10 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 8 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Day 29 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 57 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 90 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 180 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 365 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.
[b]Previously Vaccinated means received either the 2017-2018 or 2018-2019 Seasonal Vaccine.
[c] Not Previously Vaccinated means received neither the 2017-2018 or 2018-2019 Seasonal Vaccine.

Tables with similar format

Table 46: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 47: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 48: Summaries of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 49: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study, Study Arm, and Previous Vaccination, Per Protocol Population

Table 50: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 51: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 52: Summaries of Neutralizing Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 53: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

[Implementation Note: NAI titers are only assessed for all study groups for Day 1 and Day 29 and assessed for study groups 1, 2 and 3 for the rest of the timepoints.]

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 8 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 57 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x	xx.x
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 90 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x	xx.x
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Day 118 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Day 180 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Day 365 Post Vaccination 1						
n	x	x	x	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Tables with similar format:

Table 54: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population[*¥]

Table 55: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population[*¥]

Table 56: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Colorado/06/2017 (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population[*¥]

Table 57: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 58: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 59: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 60: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Colorado/06/2017 (B Victoria lineage) (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population[*¥]

Table 61: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

[Implementation Note: NAI titers are only assessed for all study groups for Day 1 and Day 29 and assessed for study groups 1, 2 and 3 for the rest of the timepoints.]

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 1 (Pre-Vaccination 1)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 8 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 29 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 57 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 90 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 180 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 365 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Tables with similar format:

Table 62: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 63: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 64: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Table 65: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

[Implementation Note: NAI titers are only assessed for all study groups for Day 1 and Day 29 and assessed for study groups 1, 2 and 3 for the rest of the timepoints.]

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]	Previously Vaccinated[b]	Not Previously Vaccinated[c]
Day 1 (Pre-Vaccination 1)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 8 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 29 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
Day 57 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 90 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 180 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A
Day 365 Post Vaccination 1												
n	x	x	x	x	x	x	N/A	N/A	N/A	N/A	N/A	N/A
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	N/A	N/A	N/A	N/A	N/A	N/A
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	N/A	N/A	N/A	N/A	N/A	N/A

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	N/A	N/A	N/A	N/A	N/A	N/A
GMFR (95% CI)	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)	N/A	N/A	N/A	N/A	N/A	N/A

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.
[b]Previously Vaccinated means received either the 2017-2018 or 2018-2019 Seasonal Vaccine.
[c] Not Previously Vaccinated means received neither the 2017-2018 or 2018-2019 Seasonal Vaccine.

Tables with similar format:

Table 66: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 67: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 68: Summaries of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Table 69: Summaries of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Modified Intent-to-Treat Population

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
A/Brisbane/02/2018 IVR-190 (H1N1)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
A/Kansas/14/2017 (H3N2)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Phuket/3073/2013 (B Yamagata lineage)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Maryland/15/2016 BX-69A (B Victoria lineage)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1						

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table with similar format:

Table 70: Summaries of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Per Protocol Population

Table 71: Summaries of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Kansas/14/2017 (H3N2)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
B/Phuket/3073/2013 (B Yamagata lineage)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
B/Maryland/15/2016 BX-69A (B Victoria lineage)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table 72: Summaries of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

A/Kansas/14/2017 (H3N2)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

B/Phuket/3073/2013 (B Yamagata lineage)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

B/Maryland/15/2016 BX-69A (B Victoria lineage)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.
[b]Previously Vaccinated means received either the 2017-2018 or 2018-2019 Seasonal Vaccine.
[c] Not Previously Vaccinated means received neither the 2017-2018 or 2018-2019 Seasonal Vaccine.

Table 73: Summaries of Neutralizing Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Modified Intent-to-Treat Population

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
A/Brisbane/02/2018 IVR-190 (H1N1)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
A/Kansas/14/2017 (H3N2)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Phuket/3073/2013 (B Yamagata lineage)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Maryland/15/2016 BX-69A (B Victoria lineage)						
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	-	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table with similar format:

Table 74: Summaries of Neutralizing Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Per Protocol Population

Table 75: Summaries of Neutralizing Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Kansas/14/2017 (H3N2)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x		x		x		x		x	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)	
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x		x		x		x		x	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)	
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)	
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)	
GMFR (95% CI)	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)		xx.x (xx.x,xx.x)	
B/Phuket/3073/2013 (B Yamagata lineage)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)
B/Maryland/15/2016 BX-69A (B Victoria lineage)												
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table 76: Summaries of Neutralizing Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
A/Kansas/14/2017 (H3N2)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x		x		x		x		x	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)	
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x		x		x		x		x	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)		xxx.x (xxx.x,xxx.x)	
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)	
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)		xx (xx, xx)	
GMFR (95% CI)	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)		xx.x (xx.x,xx.x)	

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
B/Phuket/3073/2013 (B Yamagata lineage)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
B/Maryland/15/2016 BX-69A (B Victoria lineage)												
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)	xxx.x (xxx.x, xxx.x)
Ratio of GMTs[a]	-	-	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Day 118 Post Vaccination 1												
n	x	x	x	x	x	x	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	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)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.
[b]Previously Vaccinated means received either the 2017-2018 or 2018-2019 Seasonal Vaccine.
[c] Not Previously Vaccinated means received neither the 2017-2018 or 2018-2019 Seasonal Vaccine.

Table 77: Summaries of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Modified Intent-to-Treat Population

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)
A/Brisbane/02/2018 IVR-190 (H1N1)			
Day 90 Post Vaccination 1 (Baseline)			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
A/Kansas/14/2017 (H3N2)			
Day 90 Post Vaccination 1 (Baseline)			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)
B/Phuket/3073/2013 (B Yamagata lineage)			
Day 90 Post Vaccination 1 (Baseline)			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
B/Maryland/15/2016 BX-69A (B Victoria lineage)			
Day 90 Post Vaccination 1 (Baseline)			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table with similar format:

Table 78: Summaries of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strains by Study Day and Study Arm, Per Protocol Population

Table 79: Summaries of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Baseline Serostatus, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)						
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
A/Kansas/14/2017 (H3N2)						
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)	
B/Phuket/3073/2013 (B Yamagata lineage)						
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Maryland/15/2016 BX-69A (B Victoria lineage)						
	Seropositive	**Seronegative**	**Seropositive**	**Seronegative**	**Seropositive**	**Seronegative**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Table 80: Summaries of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strains by Study Day, Study Arm, and Previous Vaccination, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)	
A/Brisbane/02/2018 IVR-190 (H1N1)						
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
A/Kansas/14/2017 (H3N2)						
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)	
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Phuket/3073/2013 (B Yamagata lineage)						
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
B/Maryland/15/2016 BX-69A (B Victoria lineage)						
	Previously Vaccinated[b]	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**	**Previously Vaccinated[b]**	**Not Previously Vaccinated[c]**
Day 90 Post Vaccination 1 (Baseline)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x

Time Point	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)	
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.
[b]Previously Vaccinated means received either the 2017-2018 or 2018-2019 Seasonal Vaccine.
[c] Not Previously Vaccinated means received neither the 2017-2018 or 2018-2019 Seasonal Vaccine.

Table 81: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Michigan/84/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Titer ≥ 1:40 - %(95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 8 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 57 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 90 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 180 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
GMFR (95% CI)	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)
Day 365 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Titer ≥ 1:40 - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer
[a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.

Tables with similar format:

Table 82: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Kenya/105/2017 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 83: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Louisiana/13/2017 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 84: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Aksaray/4048/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 85: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Shandonglaicheng/1763/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 86: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Michigan/84/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 87: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Kenya/105/2017 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 88: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Louisiana/13/2017 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 89: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Aksaray/4048/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 90: Summaries of Hemagglutination Inhibition Antibody Against Heterologous H3 Influenza Strain A/Shandonglaicheng/1763/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 91: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Michigan/84/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 8 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 57 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
Day 90 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 118 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 180 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)
Day 365 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	-	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	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)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer [a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.						

Tables with similar format:

Table 92: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Kenya/105/2017 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 93: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Aksaray/4048/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 94: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Shandonglaicheng/1763/2016 [H3N2] by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 95: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Michigan/84/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 96: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Kenya/105/2017 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 97: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Aksaray/4048/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 98: Summaries of Neutralizing Antibody Against Heterologous H3 Influenza Strain A/Shandonglaicheng/1763/2016 [H3N2] by Study Day and Study Arm, Per Protocol Population*¥

Table 99: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N1 NA Antigen from A/Oman/5532/2017 H6N1 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)
Day 1 (Pre-Vaccination 1)			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Day 8 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 29 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 57 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)
Day 90 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 118 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 180 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)
Day 365 Post Vaccination 1			
n	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Ratio of GMTs (95% CI)[a]	-	xx.x (xx.x, xx.x)	xx.x xx.x (xx.x, xx.x)
Seroconversion - % (95% CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)	xx.x (xx.x,xx.x)

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)
N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer [a]Ratio of GMTs is defined as the ratio of the GMT from the adjuvanted group divided by the GMT from the corresponding unadjuvanted group. Confidence intervals for the ratio of GMTs will use the Delta Method.			

Tables with similar format:

Table 100: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N1 NA Antigen from A/Cameroon/9766/2017 H6N1 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 101: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Human/Hubei/3/2005 H3N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 102: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Louisiana/13/2017 H6N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 103: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Townsville/51/2016 H6N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 104: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Aksaray/4048/2016 H6N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population*¥

Table 105: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N1 NA Antigen from A/Oman/5532/2017 H6N1 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 106: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N1 NA Antigen from A/Cameroon/9766/2017 H6N1 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 107: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Human/Hubei/3/2005 H3N2 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 108: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Louisiana/13/2017 H6N2 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 109: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Townsville/51/2016 H6N2 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 110: Summaries of Neuraminidase Inhibition Antibody Against Heterologous N2 NA Antigen from A/Aksaray/4048/2016 H6N2 Strain by Study Day and Study Arm, Per Protocol Population*¥

Table 111: Summary Statistics of Influenza Specific-IgG B Memory Cells (Spot Forming Cells per Million PBMC) by Study Day and Study Arm, Per Protocol Population

Time Point	Statistic	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)	All Subjects (N = X)
Day 1 (Pre-Vaccination 1)	n	x	x	x	x	x	x	x
	Mean (95 %)	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)	xx.x (xx.x, xx.x)
	GM (95 %)	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)	xx.x (xx.x, xx.x)
	Median (Min, Max)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 29 Post Vaccination 1								
	n	x	x	x	x	x	x	x
	Mean (95 %)	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)	xx.x (xx.x, xx.x)
	GM (95 %)	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)	xx.x (xx.x, xx.x)
	Median (Min, Max)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
	Mean absolute difference from Baseline (95%CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 90 Post Vaccination 1								
	n	x	x	x	x	x	x	x
	Mean (95 %)	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)	xx.x (xx.x, xx.x)
	GM (95 %)	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)	xx.x (xx.x, xx.x)
	Median (Min, Max)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
	Mean absolute difference from Baseline (95%CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

N = Number of subjects in the Per Protocol Population; n = Number of subjects with available results

Tables with similar format:

Table 112: Summary Statistics of Influenza Specific-IgM B Memory Cells by Study Day and Study Arm, Per Protocol Population

Table 113: Summary Statistics of Influenza Specific-IgA B Memory Cells by Study Day and Study Arm, Per Protocol Population

Table 114: Summary Statistics of Influenza Specific Plasmablasts by Study Day and Study Arm, Per Protocol Population

Time Point	Statistic	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)	All Subjects (N = X)
Day 1 (Pre-Vaccination 1)	n	x	x	x	x	x	x	x
	Mean (95 %)	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)	xx.x (xx.x, xx.x)
	GM (95 %)	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)	xx.x (xx.x, xx.x)
	Median (Min, Max)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Day 8 Post Vaccination 1								
	n	x	x	x	x	x	x	x
	Mean (95 %)	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)	xx.x (xx.x, xx.x)
	GM (95 %)	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)	xx.x (xx.x, xx.x)
	Median (Min, Max)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
	Mean absolute difference from Baseline (95%CI)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

N = Number of subjects in the Per Protocol Population; n = Number of subjects with available results

Table with similar format:

Table 115: Summary Statistics of the Number of Influenza Specific Tfh Cells by Study Day and Study Arm, Per Protocol Population

Table 116: Summaries of Functioning Non-Neutralizing Fc-effector Antibodies Against 2018/2019 QIV Strains by Study Day and Study Arm, Per Protocol Population

Time Point	Group 1 Fluzone (N=X)	Group 2 Fluzone + AF03 (N=X)	Group 3 Fluzone + Advax-CpG (N=X)	Group 4 Flublok (N=X)	Group 5 Flublok + AF03 (N=X)	Group 6 Flublok + Advax-CpG (N=X)
A/Michigan/45/2015 X-275 (H1N1)						
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
GMFR (95% CI)	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)
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
GMFR (95% CI)	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)
A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2)						
Day 1 (Pre-Vaccination 1)						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
GMFR (95% CI)	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)
Day 29 Post Vaccination 1						
n	x	x	x	x	x	x
GMT (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
GMFR (95% CI)	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)
Repeat for **B/Phuket/3073/2013 (B Yamagata lineage)**						
Repeat for **B/Maryland/15/2016 BX-69A (B lineage)**						

N = Number of subjects in the Modified Intent-to-Treat Population; n = Number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.

14.3 Safety Data

14.3.1 Displays of Adverse Events

Table 117: Overall Summary of Adverse Events- Safety Population*¥

	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
Subjects[a] with	n	%	n	%	n	%	n	%	n	%	n	%	n	%
At least one local solicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one grade 3 local solicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one systemic solicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one grade 3 systemic solicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one unsolicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one related unsolicited adverse event	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
Not yet assessed														
At least one severe (Grade 3) unsolicited adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Related	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Unrelated	x	x	x	x	x	x	x	x	x	x	x	x	x	x

	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)		All Subjects (N=X)	
Subjects[a] with	n	%	n	%	n	%	n	%	n	%	n	%	n	%
At least one serious adverse event[b]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one related, serious adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one adverse event leading to early termination[c]	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one medically attended adverse event	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one adverse event of special interest	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one new onset chronic medical condition	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one potentially immune mediated medical condition	x	x	x	x	x	x	x	x	x	x	x	x	x	x
At least one abnormal clinical safety laboratory adverse event	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

N = Number of subjects in the Safety Population
[a] Subjects are counted once for each category regardless of the number of events.
[b] A listing of Serious Adverse Events is included in Tab AE SAE Listing.
[c] As reported on the Adverse Event eCRF.

Table 118: Adverse Events Occurring in 5% of Subjects in Any Study Arm by MedDRA System Organ Class and Preferred Term, and Study Arm - Safety Population

Preferred Term	MedDRA System Organ Class	Group 1 Fluzone (N=X)			Group 2 Fluzone + AF03 (N=X)			Group 3 Fluzone + Advax-CpG (N=X)			Group 4 Flublok (N=X)			Group 5 Flublok + AF03 (N=X)			Group 6 Flublok + Advax-CpG (N=X)			All Subjects (N=X)		
		n	%	Events	n	%	Events	n	%	Events												
Serious Adverse Events																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	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																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc	Etc																					

N = Number of subjects in the Safety Population (number of subjects at risk).
n = Number of subjects reporting event.
Events= total frequency of events reported.

14.3.1.1 Solicited Adverse Events

Table 119: Number and Percentage of Subjects Experiencing Solicited Events with 95% Confidence Intervals by Symptom and Study Arm – Safety Population

Symptom	Group 1 Fluzone (N=X)			Group 2 Fluzone + AF03 (N=X)			Group 3 Fluzone + Advax-CpG (N=X)			Group 4 Flublok (N=X)			Group 5 Flublok + AF03 (N=X)			Group 6 Flublok + Advax-CpG (N=X)		
	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Any Symptom	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x	x	xx	x.x, x.x
Any Systemic Symptom																		
Fever																		
Feverishness																		
Fatigue																		
Malaise																		
Myalgia																		
Arthralgia																		
Headache																		
Nausea																		
Any Local Symptom																		
Pain																		
Tenderness																		
Pruritus																		
Ecchymosis																		
Ecchymosis (measurement)																		
Erythema																		
Erythema (measurement)																		
Induration/Swelling																		

Symptom	Group 1 Fluzone (N=X)			Group 2 Fluzone + AF03 (N=X)			Group 3 Fluzone + Advax-CpG (N=X)			Group 4 Flublok (N=X)			Group 5 Flublok + AF03 (N=X)			Group 6 Flublok + Advax-CpG (N=X)		
	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Induration/Swelling (measurement)																		

N = Number of subjects in the Safety Population who received any study vaccination.
95% CI estimated using Clopper-Pearson exact method

Table 120: Logistic Regression Model to Evaluate the Relationship of Treatment with Reporting Any Local Event Post First Study Vaccination - Safety Population

Model Parameter	Parameter Category	Parameter Estimate	SE	p-value	Odds Ratio	95%CI
Intercept	N/A	xxx.x	xxx.x	x.xxx	-	-
Treatment	Fluzone	-	-	-	-	-
	Fluzone + AF03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	Fluzone + Advax-CpG	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	Flublok	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	Flublok + AF03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	Flublok + Advax-CpG	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x

N = Number of subjects in the safety population.

Table with similar format:

Table 121: Logistic Regression Model to Evaluate the Relationship of Treatment with Reporting Any Systemic Event Post First Study Vaccination - Safety Population

Table 122: Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity and Study Arm Post First Study Vaccination – Safety Population*

Symptom	Severity	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Any Symptom	None	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)
	Mild												
	Moderate												
	Severe												
Any Systemic Symptom	None	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)
	Mild												
	Moderate												
	Severe												
Fever	None												
	Mild												
	Moderate												
	Severe												
Feverishness	None												
	Mild												
	Moderate												
	Severe												
Fatigue	None												
	Mild												
	Moderate												
	Severe												
Malaise	None												

Symptom	Severity	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
	Mild												
	Moderate												
	Severe												
Myalgia	None												
	Mild												
	Moderate												
	Severe												
Arthralgia	None												
	Mild												
	Moderate												
	Severe												
Headache	None												
	Mild												
	Moderate												
	Severe												
Nausea	None												
	Mild												
	Moderate												
	Severe												
Any Local Symptom	None												
	Mild												
	Moderate												
	Severe												

Symptom	Severity	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Pain	None												
	Mild												
	Moderate												
	Severe												
Tenderness	None												
	Mild												
	Moderate												
	Severe												
Pruritus	None												
	Mild												
	Moderate												
	Severe												
Ecchymosis	None												
	Mild												
	Moderate												
	Severe												
Ecchymosis (measurement)	None												
	Mild												
	Moderate												
	Severe												
Erythema	None												
	Mild												

Symptom	Severity	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
	Moderate												
	Severe												
Erythema (measurement)	None												
	Mild												
	Moderate												
	Severe												
Induration/Swelling	None												
	Mild												
	Moderate												
	Severe												
Induration/Swelling (measurement)	None												
	Mild												
	Moderate												
	Severe												

N = Number of subjects in the Safety Population.
95% CI estimated using Clopper-Pearson exact method.
Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

Table 123: Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Severity, Day Post Dose, and Study Arm Post First Study Vaccination - Safety Population

Symptom	Severity	Pre-Vac		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8+	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)																					
Any Symptom	None																				
	Mild																				
	Moderate																				
	Severe																				
Any Systemic Symptom	None																				
	Mild																				
	Moderate																				
	Severe																				
Fever	None																				
	Mild																				
	Moderate																				
	Severe																				
Feverishness	None																				
	Mild																				
	Moderate																				
	Severe																				
Fatigue	None																				
	Mild																				
	Moderate																				
	Severe																				
Malaise	None																				

Symptom	Severity	Pre-Vac		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8+	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Mild																				
	Moderate																				
	Severe																				
Myalgia	None																				
	Mild																				
	Moderate																				
	Severe																				
Arthralgia	None																				
	Mild																				
	Moderate																				
	Severe																				
Headache	None																				
	Mild																				
	Moderate																				
	Severe																				
Nausea	None																				
	Mild																				
	Moderate																				
	Severe																				
Any Local Symptom	None																				
	Mild																				
	Moderate																				
	Severe																				
Pain	None																				
	Mild																				

Symptom	Severity	Pre-Vac		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8+	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Moderate																				
	Severe																				
Tenderness	None																				
	Mild																				
	Moderate																				
	Severe																				
Pruritus	None																				
	Mild																				
	Moderate																				
	Severe																				
Ecchymosis	None																				
	Mild																				
	Moderate																				
	Severe																				
Ecchymosis (measurement)	None																				
	Mild																				
	Moderate																				
	Severe																				
Erythema	None																				
	Mild																				
	Moderate																				
	Severe																				
Erythema (measurement)	None																				
	Mild																				
	Moderate																				

Symptom	Severity	Pre-Vac		Post-Vac		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8+	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Severe																				
Induration/Swelling	None																				
	Mild																				
	Moderate																				
	Severe																				
Induration/Swelling (measurement)	None																				
	Mild																				
	Moderate																				
	Severe																				
[Repeat for all study arms]																					

N = Number of subjects in the Safety Analysis Population. Severity is the maximum severity reported post vaccination for each subject for each day.

14.3.1.2 Unsolicited Adverse Events

Table 124: Serious Adverse Events and All Unsolicited Adverse Events Occurring from Day 1 through Day 365 following the First Vaccination, in Subjects in Any Study Arm by MedDRA System Organ Class and Preferred Term, and by Study Arm – Safety Population

Preferred Term	MedDRA System Organ Class	Group 1 Fluzone (N=X)			Group 2 Fluzone + AF03 (N=X)			Group 3 Fluzone + Advax-CpG (N=X)			Group 4 Flublok (N=X)			Group 5 Flublok + AF03 (N=X)			Group 6 Flublok + Advax-CpG (N=X)			All Subjects (N=X)		
		n	%	Events	n	%	Events	n	%	Events												
Serious Adverse Events																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc.	Etc.																					
Unsolicited Adverse Events																						
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc	Etc																					

N = Number of subjects in the Safety Population (number of subjects at risk).
n = Number of subjects reporting event.
Events = total frequency of events reported.
SOC = system organ class
PT = preferred term

Table with similar format:

Table 125: Serious Adverse Events and All Unsolicited Adverse Events Occurring from Day 1 through Day 29 following the First Vaccination, in Subjects in Any Study Arm by MedDRA System Organ Class and Preferred Term, and by Study Arm – Safety Population

Table 126: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA System Organ Class and Preferred Term, and Study Arm – Safety Population

		Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
MedDRA System Organ Class	**MedDRA Preferred Term**	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
Any SOC	Any PT	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)	x	xx (xx-xx)
[SOC 1]	Any PT												
	[PT 1]												
	[PT 2]												
[SOC 2]	Any PT												
	[PT 1]												
	[PT 2]												

N = number of subjects in the Safety Analysis Population. This table presents number and percentage of subjects. A subject is only counted once per PT.

Table with similar format:

Table 127: Number and Percentage of Subjects Experiencing Any Unsolicited Adverse Events from Day 1 through Day 29 with 95% Confidence Intervals by MedDRA System Organ Class and Preferred Term, and Study Arm – Safety Population

Table 128: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Study Arm – Safety Population

Study Arm	MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[1]						Relationship to Treatment[2]			
					Mild		Moderate		Severe		Not Related		Related	
			n	%	n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												
Group 2: Fluzone + AF03 (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												
Group 3: Fluzone + Advax-CpG (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												

Study Arm	MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[1]						Relationship to Treatment[2]			
					Mild		Moderate		Severe		Not Related		Related	
			n	%	n	%	n	%	n	%	n	%	n	%
Group 4: Flublok (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												
Group 5: Flublok+ AF03 (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												
Group 6: Flublok + Advax-CpG (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT												
		[PT 1]												
		[PT 2]												
	[SOC 2]	Any PT												
		[PT 1]												
		[PT 2]												

Note: N = Number of subjects in the Safety Analysis Population.
[1] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.
[2] For relationship, a subject is only counted once per preferred term and is summarized according to their closest relationship.

Table with similar format:

Table 129: Number and Percentage of Subjects Experiencing Any Unsolicited Adverse Events from Day 1 through Day 29 by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Study Arm – Safety Population

Table 130: Number and Percentage of Subjects Experiencing Non-Serious Related Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, and Study Arm – Safety Population*

Study Arm	MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[1]					
					Mild		Moderate		Severe	
			n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								
Group 2: Fluzone + AF03 (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								
Group 3: Fluzone + Advax-CpG (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								

Study Arm	MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[1]					
					Mild		Moderate		Severe	
			n	%	n	%	n	%	n	%
Group 4: Flublok (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								
Group 5: Flublok+ AF03 (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								
Group 6: Flublok + Advax-CpG (N=X)	Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx
	[SOC 1]	Any PT	x	xx	x	xx	x	xx	x	xx
		[PT 1]								
		[PT 2]								
	[SOC 2]	Any PT								
		[PT 1]								
		[PT 2]								

Note: N = Number of subjects in the Safety Analysis Population. This table presents number and percentage of subjects.
[1] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.

Table 131: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events Within 28 Days Post First Study Vaccination by MedDRA System Organ Class and Preferred Term, Day Post Vaccination, and Study Arm – Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Day 1-8 Post Vac 1		Day 9-29 Post Vac 1		Day 1-29 Post Vac 1	
		n	%	n	%	n	%
Group 1: Fluzone (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx

MedDRA System Organ Class	MedDRA Preferred Term	Day 1-8 Post Vac 1		Day 9-29 Post Vac 1		Day 1-29 Post Vac 1	
		n	%	n	%	n	%
Group 4: Flublok (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx

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

Table 132: Number and Percentage of Subjects Experiencing Non-Serious, Related Unsolicited Adverse Events Within 28 Days Post First Study Vaccination by MedDRA System Organ Class and Preferred Term, Day Post Vaccination and Study Arm – Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Day 1-8 Post Vac 1		Day 9-29 Post Vac 1		Day 1-29 Post Vac 1	
		n	%	n	%	n	%
Group 1: Fluzone (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx

MedDRA System Organ Class	MedDRA Preferred Term	Day 1-8 Post Vac 1		Day 9-29 Post Vac 1		Day 1-29 Post Vac 1	
		n	%	n	%	n	%
Group 4: Flublok (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)							
Any SOC	Any PT	x	xx	x	xx	x	xx
[SOC 1]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx
[SOC 2]	Any PT	x	xx	x	xx	x	xx
	[PT 1]	x	xx	x	xx	x	xx
	[PT 2]	x	xx	x	xx	x	xx

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

Table 133: Number of Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Day Post Vaccination, and Study Arm – Safety Population

			Day 1-8 Post Vac 1	Day 9-29 Post Vac 1	Day 1-29 Post Vac 1
Study Arm	**MedDRA System Organ Class**	**MedDRA Preferred Term**	**# of Events**	**# of Events**	**# of Events**
Group 1: Fluzone (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			
Group 2: Fluzone + AF03 (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			
Group 3: Fluzone + Advax-CpG (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			

			Day 1-8 Post Vac 1	Day 9-29 Post Vac 1	Day 1-29 Post Vac 1
Group 4: Flublok (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			
Group 5: Flublok+ AF03 (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			
Group 6: Flublok + Advax-CpG (N=X)	Any SOC	Any PT	x	x	x
	[SOC 1]	Any PT			
		[PT 1]			
		[PT 2]			
	[SOC 2]	Any PT			
		[PT 1]			
		[PT 2]			

14.3.2 Listing of Serious and Significant Adverse Events

Table 134: Listing of Serious Adverse Events*

[Implementation Note: If the event is ongoing (no stop date), indicate "ongoing" in the "Duration" column. If more than one reason is selected for the reason reported as an SAE, list all reasons in the column, separated by a comma. In the "If Not Related, Alternate Etiology" column, merge the 2 data fields for collecting alternate etiology, separate by a colon. In the CSR, Subject ID should be USUBJID (not PATID) for purposes of de-identification.]

Adverse Event	Associated with Vac #	# of Days Post Associated Dose (Duration)	# of Days Post Vac the Event Became Serious	Reason Reported as an SAE	Severity	Relationship to Study Vaccination	In Not Related, Alternative Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Study Arm: , AE Number:												
Comments:												
Subject ID: , Study Arm: , AE Number:												
Comments:												

Table 135: Listing of Adverse Events of Special Interest*

[Implementation Note: This listing is included in the tables section, as it is included in the body of the CSR. If the event is ongoing (no stop date), indicate "ongoing" in the "Duration" column. In the "If Not Related, Alternate Etiology" column, merge the 2 data fields for collecting alternate etiology, separate by a colon.]

Adverse Event	Associated with Vac #	# of Days Post Associated Vac (Duration)	SAE? Severity	Relationship to Study Vaccination	In Not Related, Alternative Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to AE	Outcome	MAAE	MedDRA System Organ Class	MedDRA Preferred Term
	Subject ID: , Study Arm: , AE Number:										
			SAE: No Mild								
	Comments:										
	Subject ID: , Study Arm: , AE Number:										
	Comments:										

Tables with similar format:

Table 136: Listing of Potentially Immune Mediated Medical Conditions*

Table 137: Listing of New Onset Chronic Medical Conditions*

Table 138: Listing of Non-Serious, Unsolicited, Moderate or Severe Adverse Events*

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 Displays of Laboratory Results

Table 139: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – All Laboratory Parameters*

Study Arm	Study Day	N	None		Mild/ Grade 1		Moderate/ Grade 2		Severe/ Grade 3		Missing	
			n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 4: Flublok (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx

N = Number of subjects in the Safety Population.

Table 140: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – White Blood Cells

Study Arm	Study Day	N	None		Mild/ Grade 1 (Low)		Mild/ Grade 1 (High)		Moderate/ Grade 2 (Low)		Moderate/ Grade 2 (High)		Severe/ Grade 3 (Low)		Severe/ Grade 3 (High)		Missing	
			n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 4: Flublok (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Day 8	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Note: N = Number of subjects in the Safety Population.

Tables with similar format:

Table 141: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Hemoglobin

Table 142: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Platelets

Table 143: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Alanine Aminotransferase (ALT)

Table 144: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Aspartate Amino Transferase (AST)

Table 145: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Total Bilirubin

Table 146: Laboratory Results by Parameter, Maximum Severity, Study Day, and Study Arm – Gamma-Glutamyl Transferase (GGT)

Table 151: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – White Blood Cells

Study Arm	Study Day	Value					Change from Baseline				
		N	Mean	Standard Deviation	Median	Min, Max	N	Mean	Standard Deviation	Median	Min, Max
Group 1: Fluzone (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx
Group 2: Fluzone + AF03 (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx
Group 3: Fluzone + Advax-CpG (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx
Group 4: Flublok (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx
Group 5: Flublok + AF03 (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx
Group 6: Flublok + Advax-CpG (N=X)	Baseline	x	xx.x	xx.x	xx	xx, xx	NA	NA	NA	NA	NA
	Day 8	x	xx.x	xx.x	xx	xx, xx	x	xx.x	xx.x	xx	xx, xx

Note: N = Number of subjects in the Safety Population.

Tables with similar format

Table 152: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – Hemoglobin

Table 153: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – Platelets

Table 154: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – Alanine Aminotransferase (ALT)

Table 155: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – Aspartate Amino Transferase (AST)

Table 156: Laboratory Summary Statistics of Value and Change from Baseline by Study Day, and Study Arm – Total Bilirubin

14.3.4.5 Clinical Laboratory Reference Ranges

(Placeholder for the CSR)

14.3.5 Abnormal Laboratory Value Listings (by Subject)

Table 162: Listing of Abnormal Laboratory Results - Chemistry

Subject ID	Study Arm	Sex	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Study Vaccination	If Not Related, Alternate Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to Result?

Table 163: Listing of Abnormal Laboratory Results - Hematology

Subject ID	Study Arm	Sex	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternate Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to Result?

14.3.6 Displays of Vital Signs

Table 164: Vital Signs by Assessment, Maximum Severity, Time Point, and Study Arm – Any Assessment

Study Arm	Study Day	N	None		Mild		Moderate		Severe		Missing	
			n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 4: Flublok (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx

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

Table with similar format

Table 165: Vital Signs by Assessment, Maximum Severity, Time Point, and Study Arm – Oral Temperature

Table 166: Vital Signs by Assessment, Maximum Severity, Study Day, and Study Arm – Systolic Blood Pressure

Study Arm	Study Day	N	None		Mild (Low)		Mild (High)		Moderate (Low)		Moderate (High)		Severe (Low)		Severe (High)		Missing	
			n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Group 1: Fluzone (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 2: Fluzone + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 3: Fluzone + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 4: Flublok (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 5: Flublok + AF03 (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Group 6: Flublok + Advax-CpG (N=X)	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	Max Severity Post Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

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

Tables with similar format:

Table 167: Vital Signs by Assessment, Maximum Severity, Study Day, and Study Arm– Diastolic Blood Pressure

Table 168: Vital Signs by Assessment, Maximum Severity, Study Day, and Study Arm – Pulse

14.4 Summary of Concomitant Medications

Table 169: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Study Arm

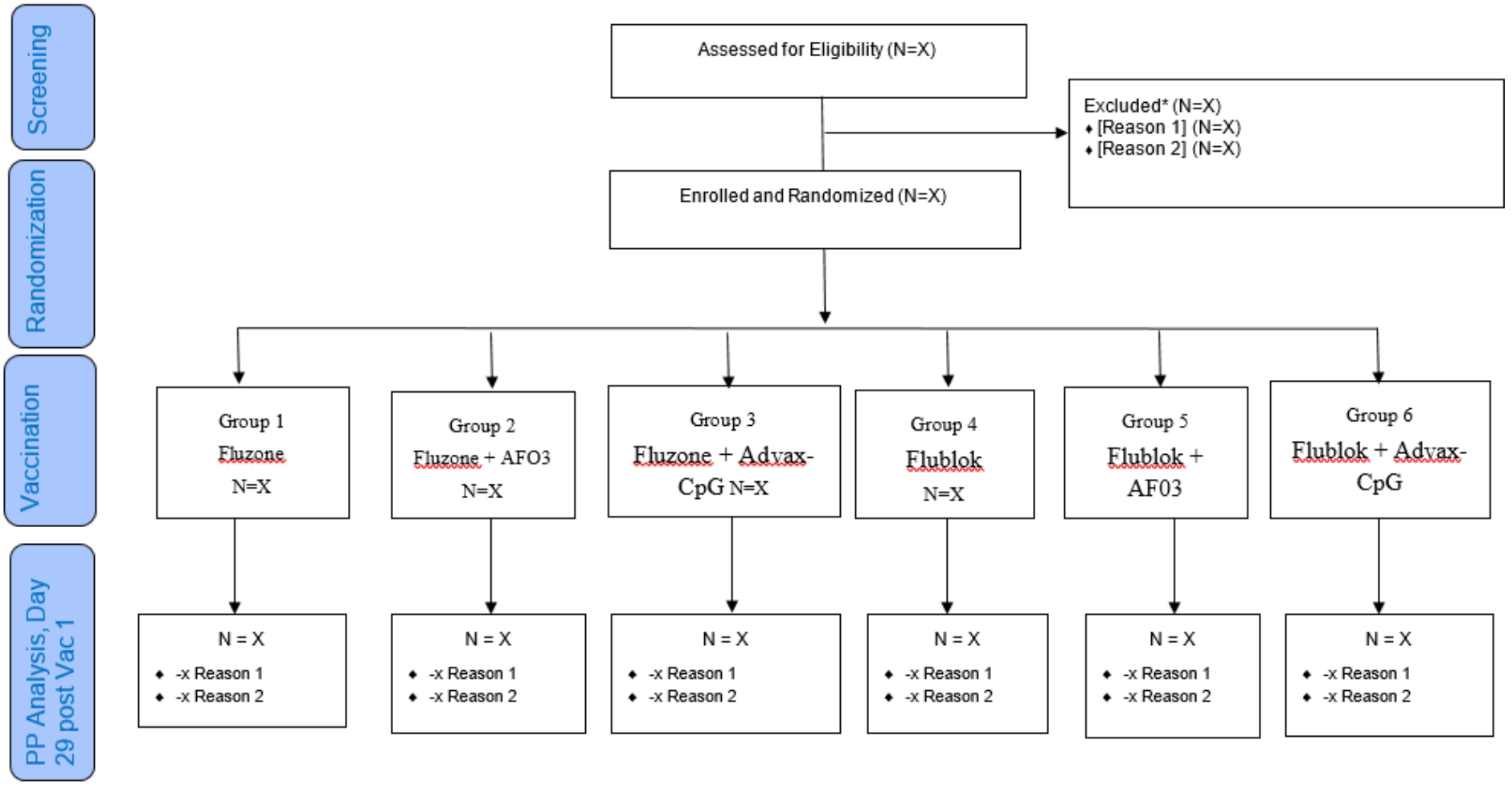
WHO Drug Code Level 1, Anatomic Group	WHO Drug Code Level 2, Therapeutic Subgroup	Group 1 Fluzone (N=X)		Group 2 Fluzone + AF03 (N=X)		Group 3 Fluzone + Advax-CpG (N=X)		Group 4 Flublok (N=X)		Group 5 Flublok + AF03 (N=X)		Group 6 Flublok + Advax-CpG (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%
Any Level 1 Codes	Any Level 2 Codes	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[ATC Level 1 - 1]	Any [ATC 1 – 1]												
	[ATC 2 - 1]												
	[ATC 2 - 2]												
	[ATC 2 - 3]												
[ATC Level 1 – 2]	[ATC 2 - 1]												
	[ATC 2 - 2]												
	[ATC 2 - 3]												

APPENDIX 2. FIGURE MOCK-UPS

LIST OF FIGURES

10.1 Disposition of Subjects

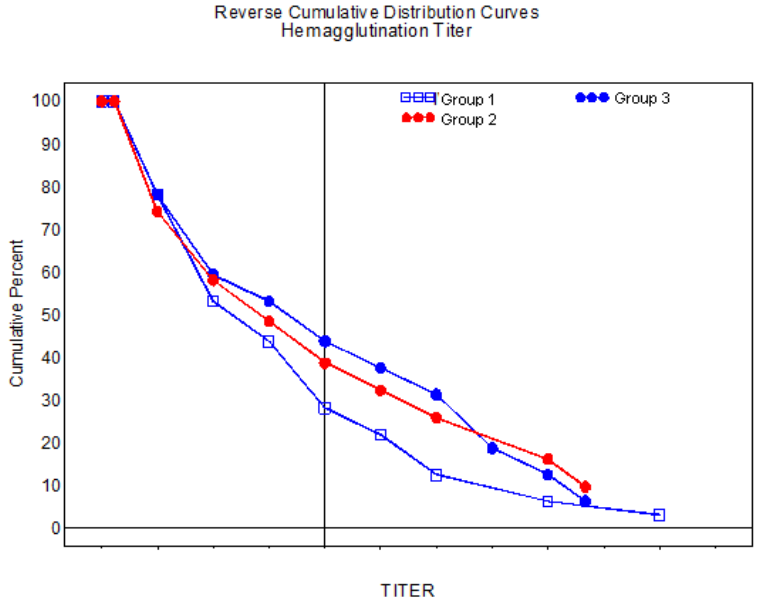
Figure 1: CONSORT Flow Diagram



14.2.2 Immunogenicity Figures

Figure 2: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2018/2019 A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: A generic sample figure is shown below. The RCD curves should be presented in a single figure with eight separate panels for each outcome day (1 (Baseline), 8, 29, 57, 90, 118, 180, and 365 post vaccination 1). Visit labels should be included in the panel headers. Within each panel individual curves should be used for each study arm (six curves). Each study arm should have a separate color and marker shape.]



Figures with similar format:

Figure 3: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 4: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 5: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 6: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Per Protocol Population

Figure 20: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 21: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 22: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Michigan/45/2015 X-275 (H1N1) by Study Day and Study Arm, Per Protocol Population

Figure 23: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2) by Study Day and Study Arm, Per Protocol Population

Figure 24: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population

Figure 25: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2018/2019 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population

[Implementation Note: The RCD curves for 2019/2020 QIV strains should be presented in a single figure with four separate panels for each outcome day (90 (Baseline),118, 180, and 365 post vaccination 1). Visit labels should be included in the panel headers. Within each panel individual curves should be used for each study arm (six curves). Each study arm should have a separate color and marker shape.]

Figure 26: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 27: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Per Protocol Population

Figure 28: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 29: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Per Protocol Population

Figure 30: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 31: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain A/Brisbane/02/2018 (H1N1) by Study Day and Study Arm, Per Protocol Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 32: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain A/Kansas/14/2017 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 33: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain A/Kansas/14/2017 (H3N2) by Study Day and Study Arm, Per Protocol Population

Figure 34: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain A/Kansas/14/2017 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 35: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 A/Kansas/14/2017 (H3N2) Strain by Study Day and Study Arm, Per Protocol Population

Figure 36: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain A/Kansas/14/2017 (H3N2) by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 37: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain A/Kansas/14/2017 (H3N2) by Study Day and Study Arm, Per Protocol Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 38: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 39: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population

Figure 40: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 41: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population

Figure 42: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: NAI titers are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 43: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain B/Phuket/3073/2013 (B Yamagata lineage) by Study Day and Study Arm, Per Protocol Population

[Implementation Note: NAI titers are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 44: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 45: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody Against 2019/2020 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population

Figure 46: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 47: Reverse Cumulative Distribution of Neutralizing Antibody Against 2019/2020 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population

Figure 48: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against QIV Strain 2019/2020 B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 49: Reverse Cumulative Distribution of Neuraminidase Inhibition Antibody Against 2019/2020 QIV Strain B/Maryland/15/2016 BX-69A (B Victoria lineage) by Study Day and Study Arm, Per Protocol Population

[Implementation Note: NAI titers against 2019/2020 QIV strains are only assessed for study arms 1, 2, and 3. Within each panel, three individual curves should be used for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

[Implementation Note: The RCD curves for Heterologous A/H3 strains should be presented in a single figure with eight separate panels for each outcome day (1 (Baseline), 8, 29, 29, 90, 118, 180, and 365 post vaccination 1). Visit labels should be included in the panel headers. Within each panel individual curves should be used for each study arm (six curves). Each study arm should have a separate color and marker shape.]

Figure 63: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Louisiana/13/2017 by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 64: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Michigan/84/2016 H3N2 by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 65: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Colombia/6639/2017 by Study Day and Study Arm, Per Protocol Population

Figure 66: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Victoria/756/2017 by Study Day and Study Arm, Per Protocol Population

Figure 67: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Kenya/105/2017 by Study Day and Study Arm, Per Protocol Population

Figure 68: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Louisiana/13/2017 by Study Day and Study Arm, Per Protocol Population

Figure 69: Reverse Cumulative Distribution of Neutralizing Antibody Against Heterologous Influenza A/H3 Strain A/Michigan/84/2016 H3N2 by Study Day and Study Arm, Per Protocol Population

[Implementation Note: The RCD curves NAI against N1 and N2 NA antigens should be presented in a single figure with eight separate panels for each outcome day (1 (Baseline), 8, 29, 29, 90, 118, 180, and 365 post vaccination 1). Visit labels should be included in the panel headers. Within each panel, three individual curves should be used for study arms 1, 2, and 3 since NAI titers are only assessed for study arms 1, 2, and 3. Each study arm should have a separate color and marker shape.]

Figure 70: Reverse Cumulative Distribution of Neuraminidase Inhibition N1 NA Antigen from A/Oman/5532/2017 H6N1 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 71: Reverse Cumulative Distribution of Neuraminidase Inhibition N1 NA Antigen from A/Cameroon/9766/2017 H6N1 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population

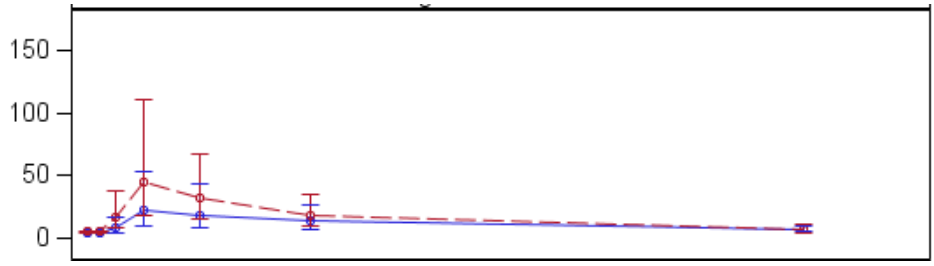
Figure 72: Reverse Cumulative Distribution of Neuraminidase Inhibition N2 NA Antigen from A/Human/Hubei/3/2005 H3N1 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 73: Reverse Cumulative Distribution of Neuraminidase Inhibition N2 NA Antigen from A/Louisiana/13/2017 H6N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 74: Reverse Cumulative Distribution of Neuraminidase Inhibition N2 NA Antigen from A/Townsville/51/2016 H6N2 Strain by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 82: Geometric Mean Titers of Hemagglutination Inhibition Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Modified Intent-to-Treat Population

[Implementation Note: A generic sample figure is shown below. Planned Study Day (1,8,57,90,118, 180,365) is plotted along the x-axis, with visit labels as tick labels. Titer is plotted on the y-axis on the log-10 scale. GMT should be plotted at each visit with upper and lower error bars for the 95% CI for each study arm with different marker shapes/colors for each study arm. Each study arm should have a separate color and marker shape. Four panels will be created with each panel representing a 2018/2019 QIV strain]



Figures with similar format:

Figure 83: Geometric Mean Titers of Hemagglutination Inhibition Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Per Protocol Population

Figure 84: Geometric Mean Titers of Neutralizing Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 85: Geometric Mean Titers of Neutralizing Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Per Protocol Population

Figure 86: Geometric Mean Titers of Neuraminidase Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Modified Intent-to-Treat Population

Figure 87: Geometric Mean Titers of Neuraminidase Antibody Against 2018/2019 QIV strains by Study Day and Study Arm, Per Protocol Population

Figure 88: Geometric Mean Titers of HA Binding Antibodies Against Different Influenza Strains by Study Day and Study Arm, Per Protocol Population

[Implementation Note: A generic sample figure is shown below. Planned Study Day (1,8,29, 57,90,118, 180,365) is plotted along the x-axis, with visit labels as tick labels. Titer is plotted on the y-axis on the log-10 scale. GMT should be plotted at each visit for each strain. Different attributes such as line color, marker shape, line style, line transparency will be used to distinguish strains within a similar grouping. Groupings provided by Sanofi will be used. Six panels will be created to represent the different study arms.]

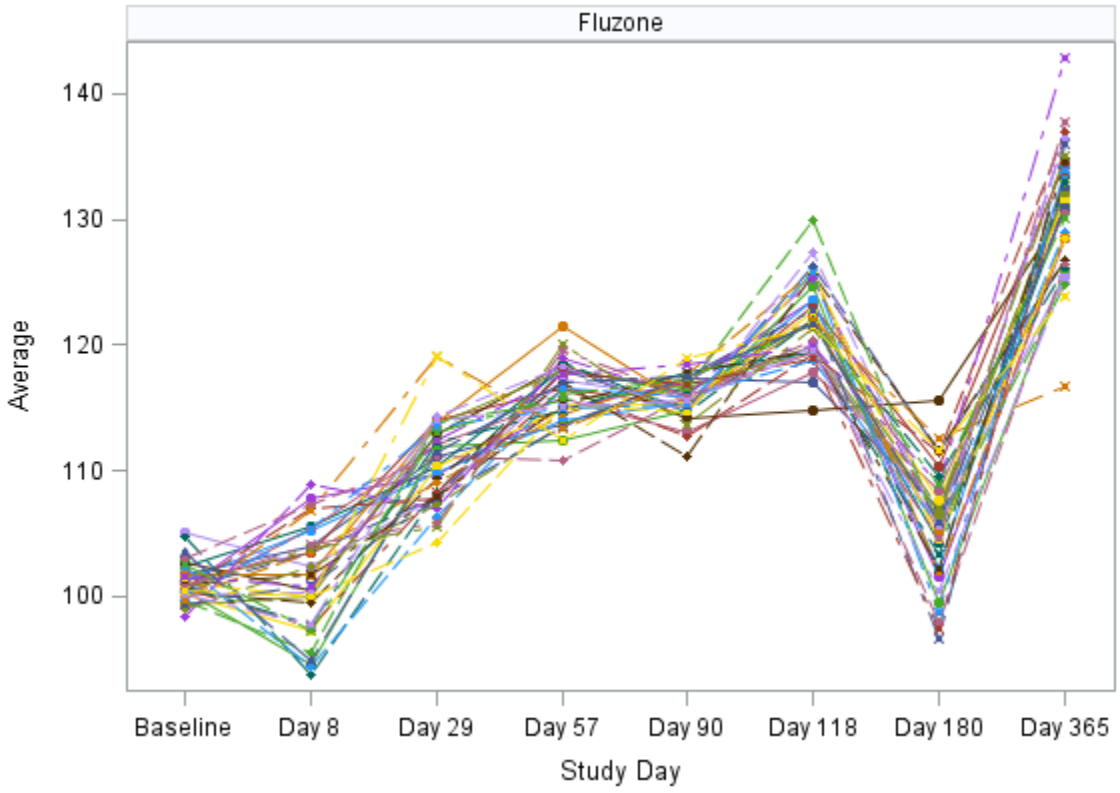


Figure 89: Geometric Mean Titers of NA Binding Antibodies Against Different Influenza NA Antigens by Study Day and Study Arm, Per Protocol Population

[Implementation Note: A generic sample figure is shown below. Planned Study Day (1,8,29,57,90,118, 180,365) is plotted along the x-axis, with visit labels as tick labels. Geometric Mean titer is plotted on the y-axis. GMT should be plotted at each visit for each of the 9 strains with different marker shapes/colors for each strain. Each strain should have a separate color and marker shape. Three panels will be created with each panel representing study arms 1,2, or 3]

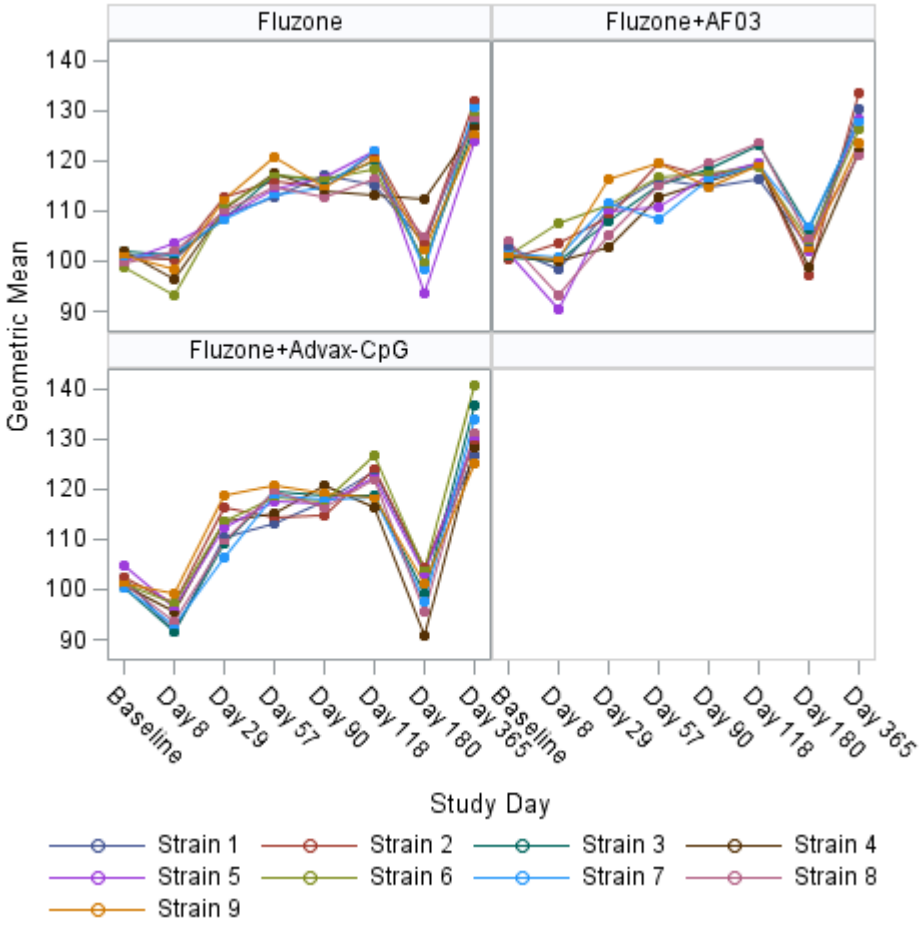


Figure 90: Association of Non-Neutralizing Fc-effector Antibody Titers and Hemagglutination Inhibition Antibody Titers against 2018/2019 QIV Strains by Study Day and Study Arm, Per Protocol Population

[Implementation Note: A generic scatter plot is shown below. HAI antibody titers are plotted along the x-axis (x-axis label: HAI Titer) and Fc-effector antibody Titers are plotted on the y-axis (y-axis label: Fc-effector Titer). Each study arm will be represented as follow: The same color will be used for the same vaccine (Flublok vs. Fluzone), the same symbol (circle, triangle, square) will be used to indicate the name adjuvant (i.e. no adjuvant, AF03, Advax), and filled vs. unfilled will be used to distinguish adjuvanted vs. unadjuvanted groups.. The spearman correlation should be calculated over all subjects and annotated within each panel as "Spearman Correlation (r=0.xx, p=0.xx)". Eight panels will be created with 4 rows to represent the four 2018/2019 QIV strains and 2 columns to represent Day 1 and Day 29.]

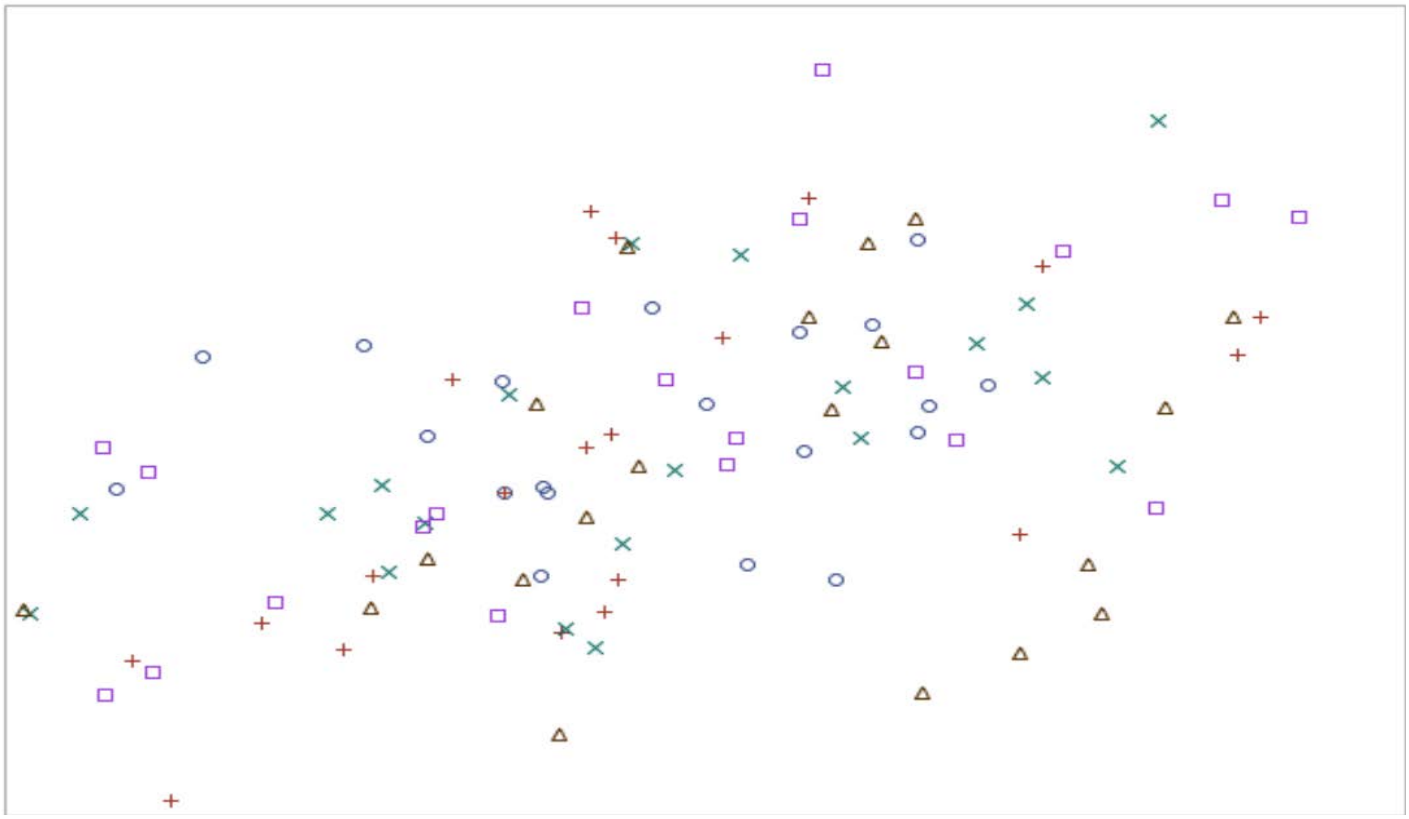


Figure with Similar format:

Figure 91: Association of Non-neutralizing Fc-effector Antibody Titers and Neutralizing Antibody Titers against 2018/2019 QIV Strains by Study Day and Study Arm, Per Protocol Population

[Implementation Note: A generic scatter plot is shown below. Neut antibody titers are plotted along the x-axis (x-axis label: Neut Titer) and Fc-effector antibody Titers are plotted on the y-axis (y-axis label: Fc-effector Titer). Each study arm should have a separate color and marker shape. The spearman correlation should be calculated over all subjects and annotated within each panel as "Spearman Correlation (r=0.xx, p=0.xx)". Eight panels will be created with 4 rows to represent the four 2018/2019 QIV strains and 2 columns to represent Day 1 and Day 29.]

Figure 92: Association of Non-neutralizing Fc-effector Antibody Titers and HAI Seroconversion Status against 2018/2019 QIV Strains by Study Arm at Day 29, Per Protocol Population

[Implementation Note: A generic sample figure is shown below. Eight panels will be created with 4 rows to represent the four 2018/2019 QIV strains]

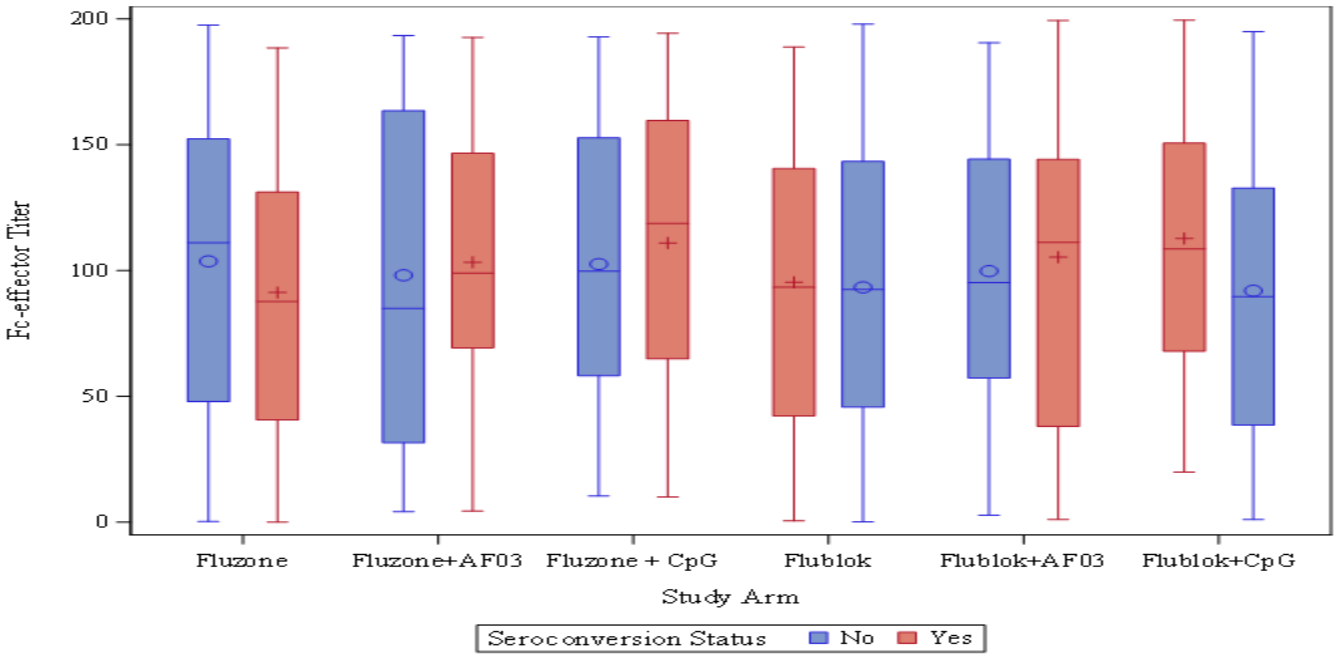


Figure with similar format:

Figure 93: Association of Non-neutralizing Fc-effector Antibody Titers and Neutralizing Antibody Seroconversion Status against 2018/2019 QIV Strains by Study Arm at Day 29, Per Protocol Population

Figure 94: Association of Non-neutralizing Fc-effector Antibody Titers and Hemagglutination Inhibition Antibody Seroprotection Status against 2018/2019 QIV Strains by Study Day and Study Arm, Per Protocol Population

[Implementation Note: A generic sample figure is shown below. Eight panels will be created with 4 rows to represent the four 2018/2019 QIV strains and 2 columns to represent Day 1 and Day 29.]

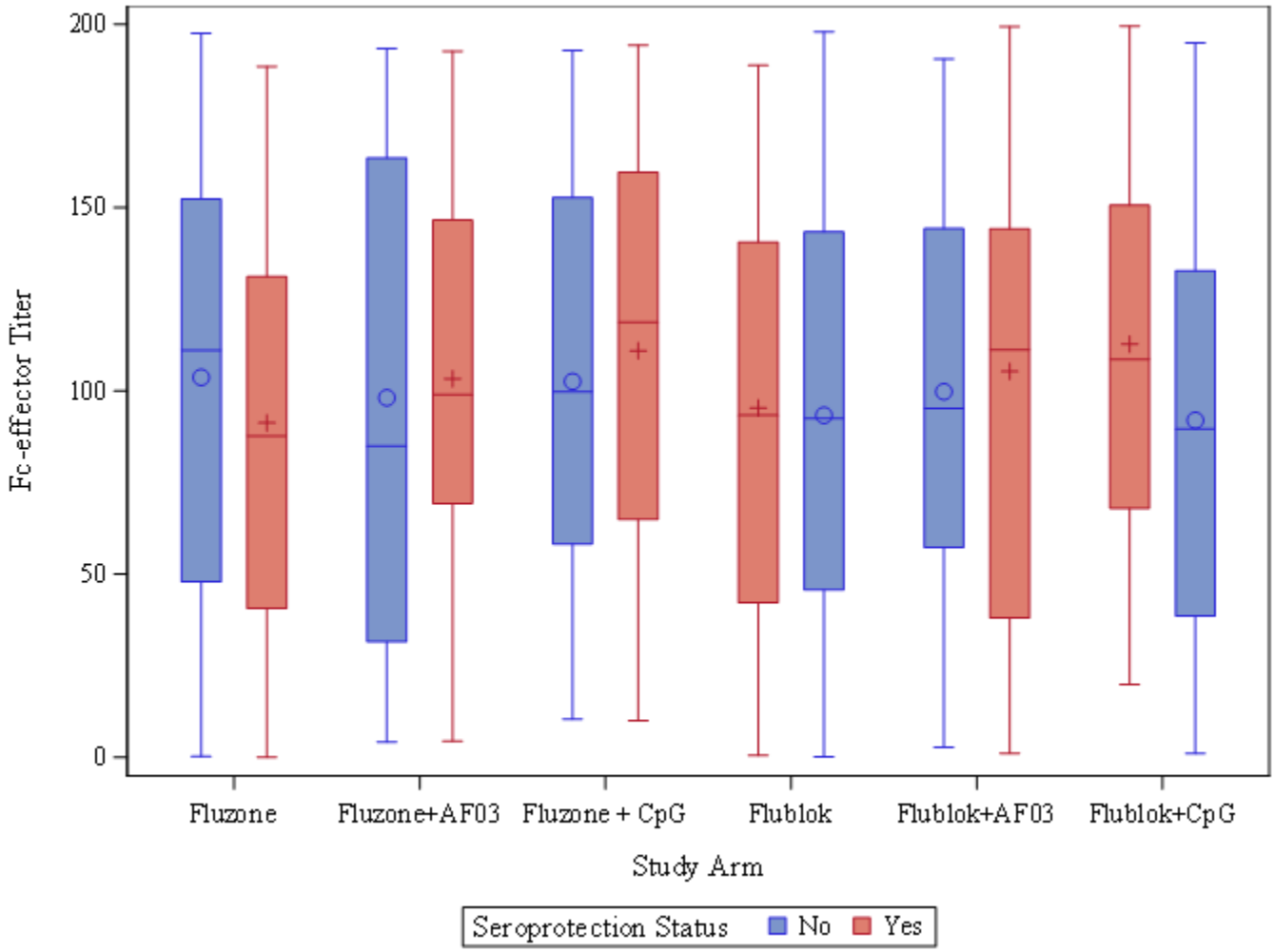


Figure with similar format:

Figure 95: Association of Non-neutralizing Fc-effector Antibody Titers and Neutralizing Antibody Seroprotection Status against 2018/2019 QIV Strains by Study Day and Study Arm, Per Protocol Population

14.3.1.1 Solicited Adverse Events

Figure 96: Maximum Severity of Solicited Systemic Symptoms per Subject by Day Post First Vaccination

[Implementation Note: A Generic figure is shown below. A ***vertical*** bar chart should be presented in 1 image file with separate panels for each study arm (6 panels: Top row: Groups 1, 2, 3; Bottom row: Groups 4, 5, 6). Axes should be labeled as follows: x-axis label: Study Day, y-axis label: Percentage of Subjects (%). The study arms should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the in the Safety Population who received the first study vaccination. Subjects are counted at most once at the maximum severity across all systemic events reported for the specified time point]

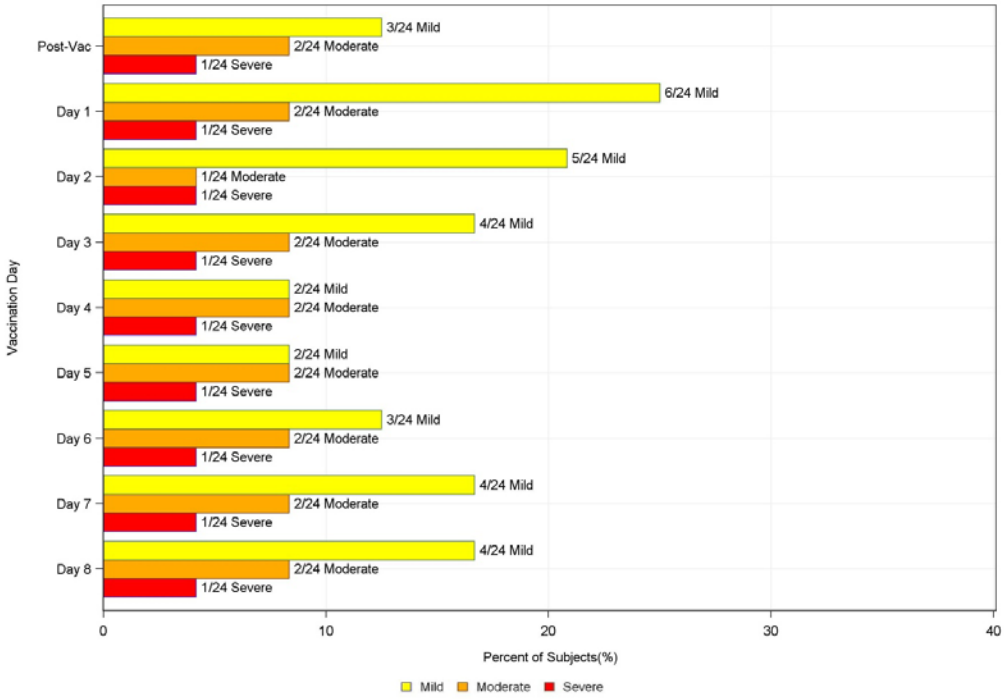


Figure with similar format:

Figure 97: Maximum Severity of Solicited Local Symptoms per Subject by Day Post First Vaccination

14.3.1.2 Unsolicited Adverse Events

Figure 98: Frequency of Unsolicited Adverse Events by MedDRA System Organ Class and Severity

[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all doses. A ***horizontal*** bar chart should be presented in 1 image file separate panels for each study arm (6 panels: Top row: Groups 1, 2, 3; Bottom row: Groups 4, 5, 6). Axes should be labeled as follows: y-axis label: System Organ Class, y-axis label: Number of Events. The study arms should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the in the Safety Population. The y-axis should present all SOCs reported by at least 1 subject and an "All Events" category. Y-axis should be sorted with "All Events first, then in decreasing order of total incidence]

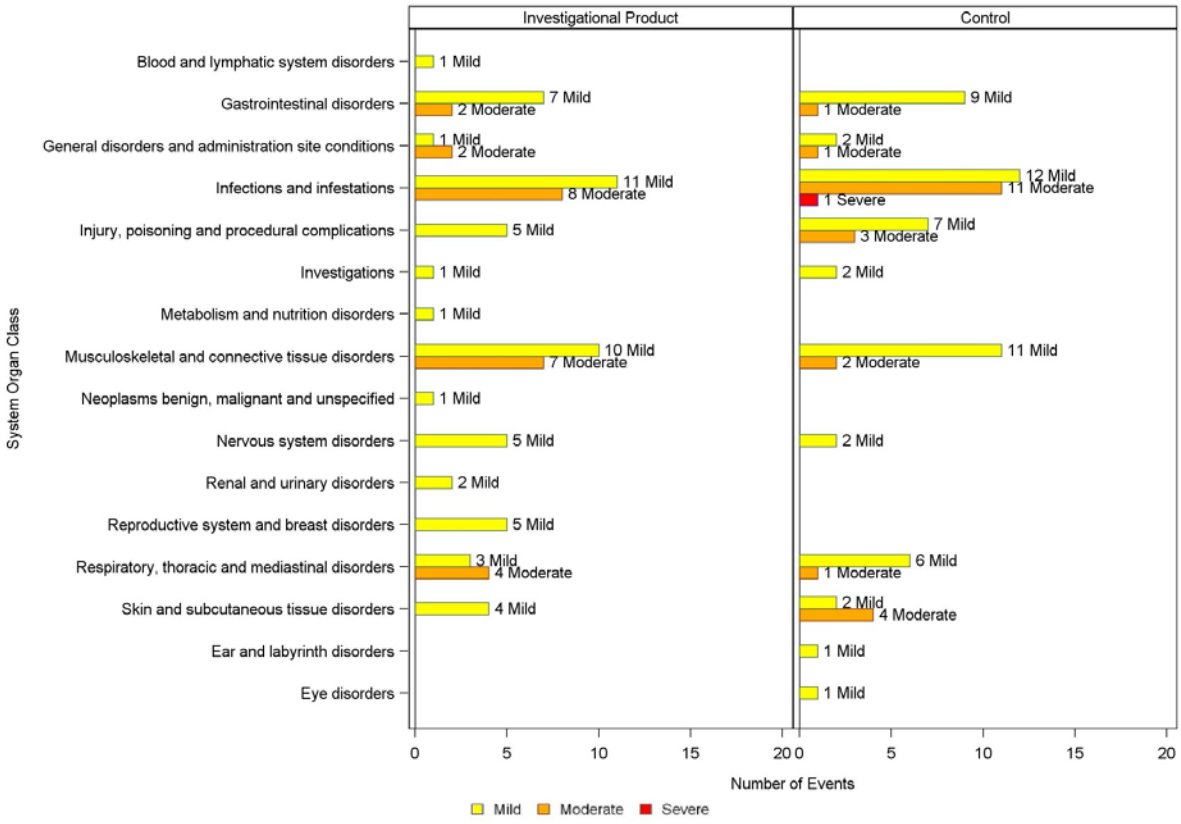


Figure 99: Incidence of Unsolicited Adverse Events by MedDRA System Organ Class and Maximum Severity

[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all doses. A ***horizontal*** bar chart should be presented in 1 image file with separate panels for each study arm (6 panels: Top row: Groups 1, 2, 3; Bottom row: Groups 4, 5, 6). Axes should be labeled as follows: y-axis label: System Organ Class, x-axis label: Percentage of Subjects (%). The study arms should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the in the Safety Population. Subjects are counted at most once at the maximum severity across for any events in the applicable SOC. The y-axis should present all SOCs reported by at least 1 subject and an "All Events" category. Y-axis should be sorted with "All Events" first then in decreasing order of total incidence]

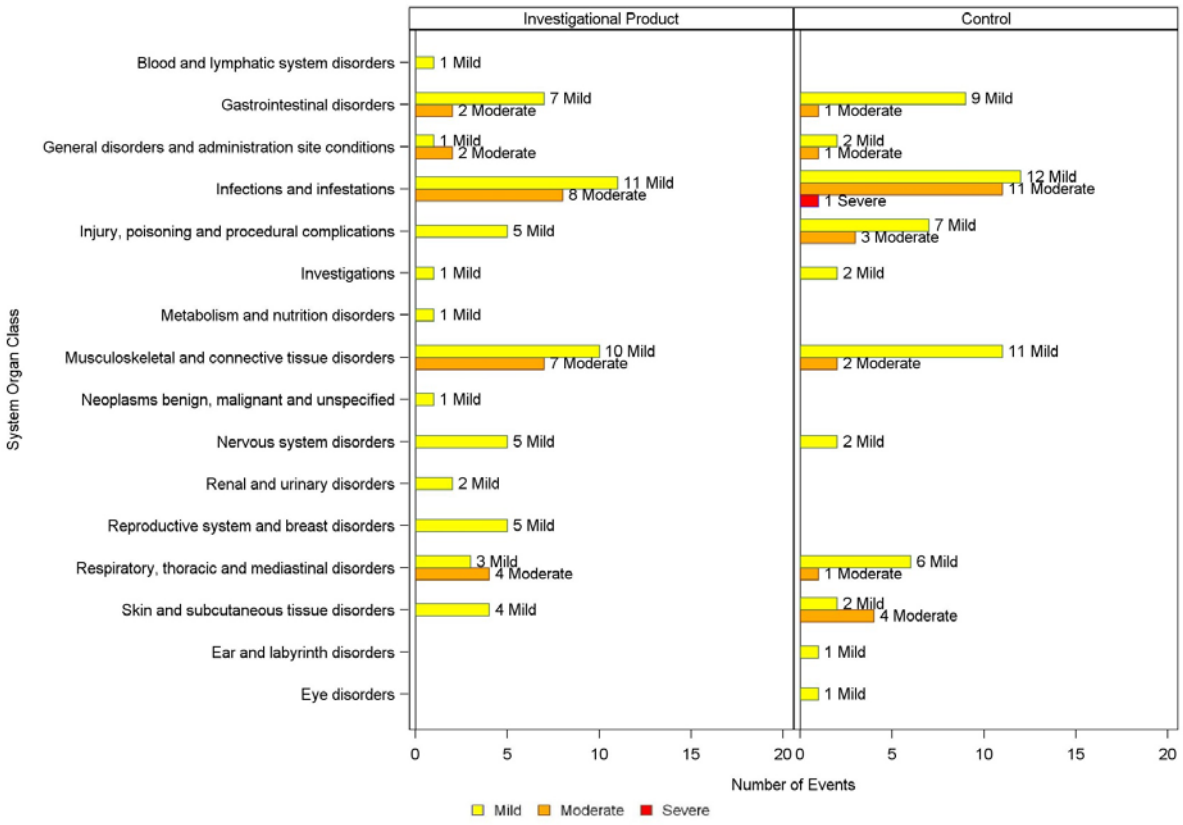


Figure 100: Frequency of Adverse Events by MedDRA System Organ Class and Relationship to Treatment

[Implementation Note: A generic sample figure is shown below. This figure includes all unsolicited events across all doses. A ***horizontal*** bar chart should be presented in 1 image file with separate panels for each study arm (6 panels: Top row: Groups 1, 2, 3; Bottom row: Groups 4, 5, 6). Axes should be labeled as follows: y-axis label: System Organ Class, y-axis label: Number of Events. The study arms should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the in the Safety Population. The y-axis should present all SOCs reported by at least 1 subject and an "All Events" category. Y-axis should be sorted with "All Events first then in decreasing order of total frequency]

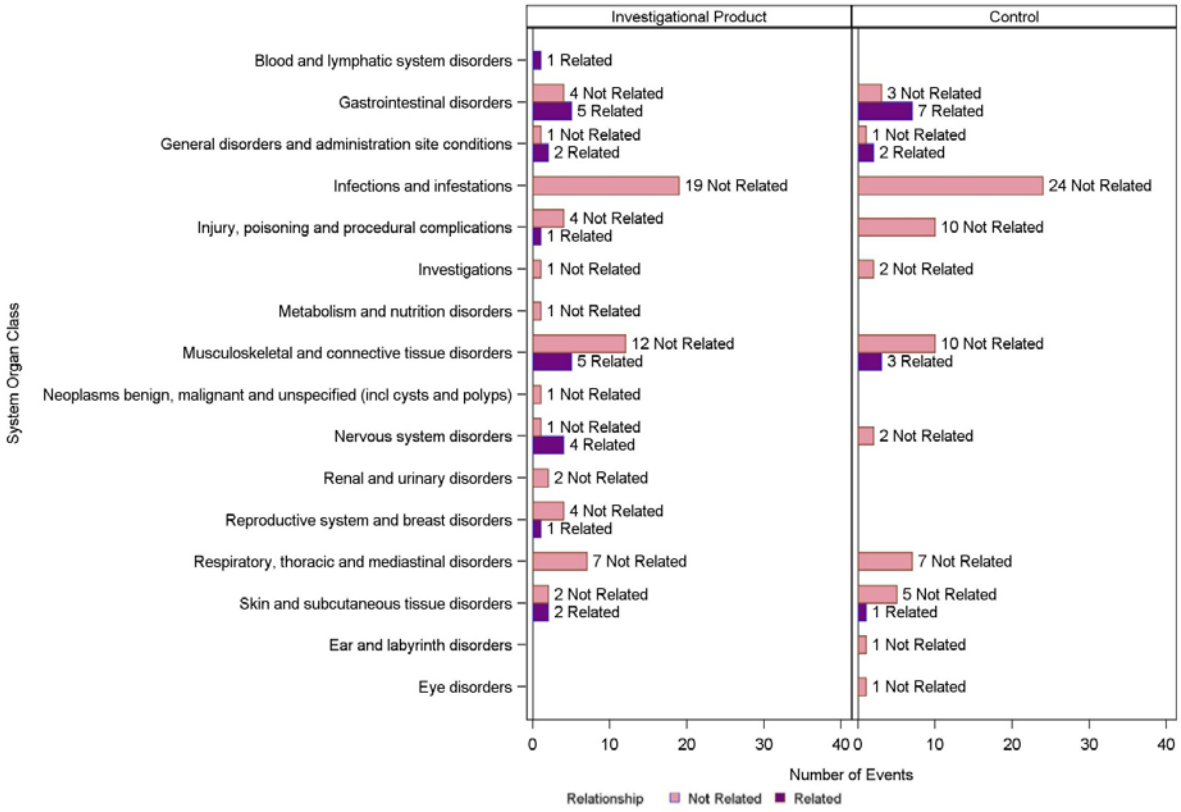
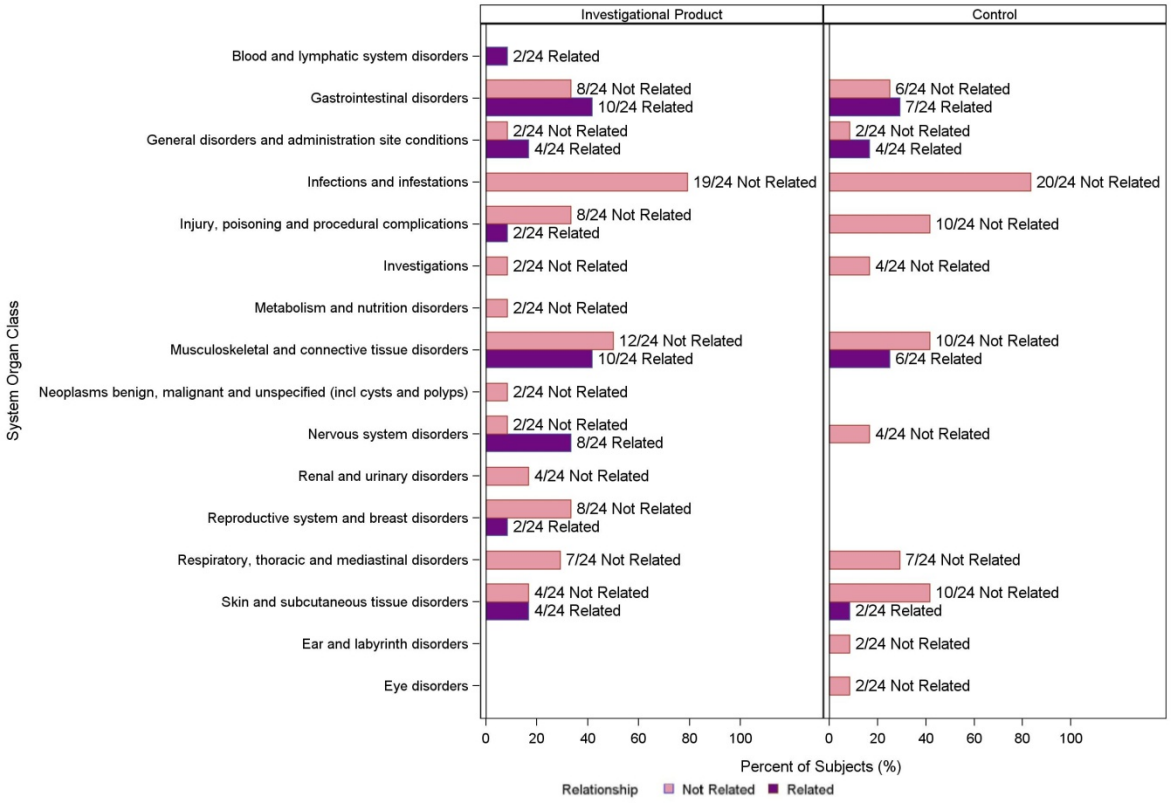


Figure 101: Incidence of Adverse Events by MedDRA System Organ Class and Relationship to Treatment

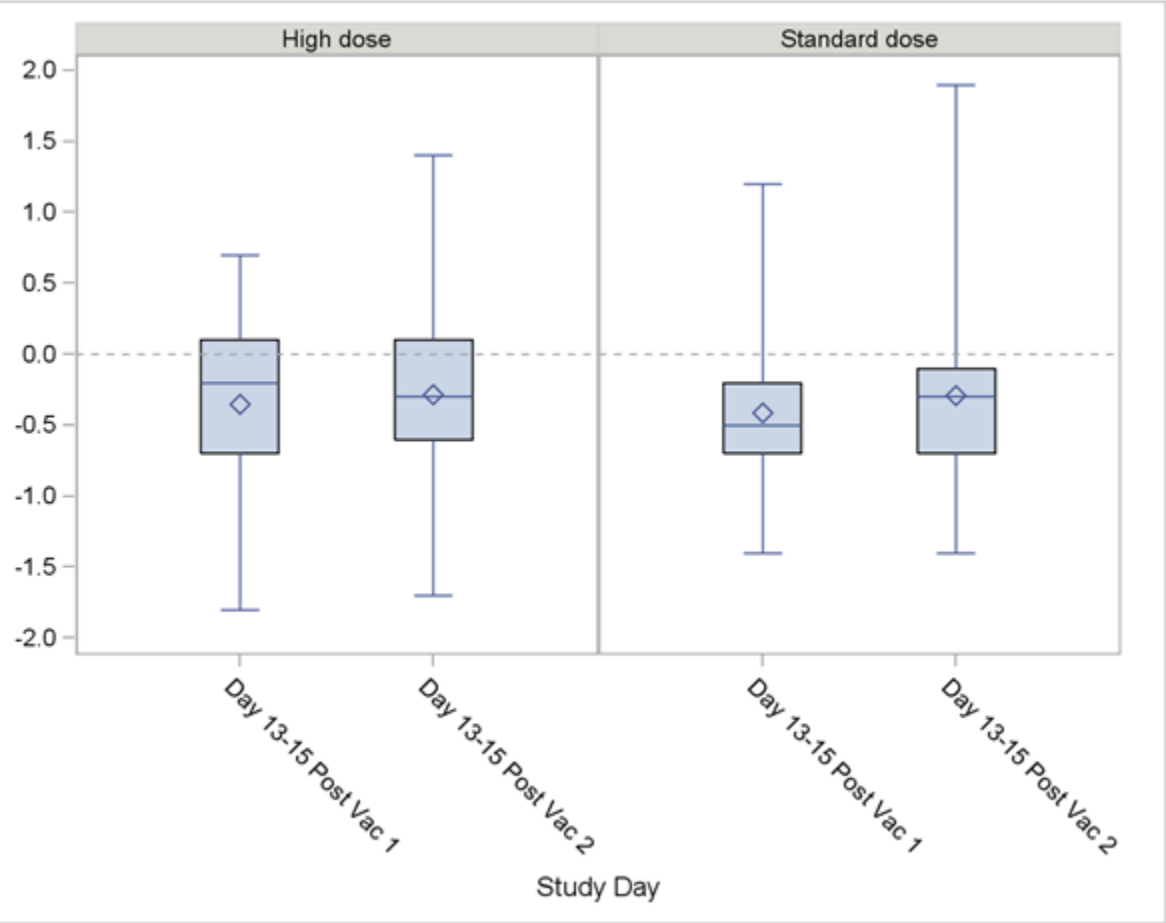
[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all doses. A ***horizontal*** bar chart should be presented in a 1 image file with separate panels for each study arm (6 panels: Top row: Groups 1, 2, 3; Bottom row: Groups 4, 5, 6). Axes should be labeled as follows: y-axis label: System Organ Class, x-axis label: Percentage of Subjects (%). The study arms should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the in the Safety Population. Subjects are counted at most once at the maximum relationship (related >not-related) across for any events in the applicable SOC. The y-axis should present all SOCs reported by at least 1 subject and an "All Events" category. Y-axis should be sorted with "All Events first, then in decreasing order of total incidence across groups]



14.3.5 Displays of Laboratory Results

Figure 102: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – White Blood Cells

[Implementation note: A generic figure is shown below. Plot should be generated with all study arms in a single image file single panel with six boxplots to represent six study arms. Y-axis should be labeled "[Parameter] Change from baseline ([units]) and x-axis will be labeled 'Study Arm'. Repeat for all clinical laboratory parameters: WBC, Hgb, PLT, ALT, AST, T. Bili, GGT, ALP, AMY, LIP, Cr]



Figures with similar format:

Figure 103: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Hemoglobin

Figure 104: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Platelets

Figure 105: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Alanine Aminotransferase (ALT)

Figure 106: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Aspartate Amino Transferase (AST)

Figure 107: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Total Bilirubin

Figure 108: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Gamma-Glutamyl Transferase (GGT)

Figure 109: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Alkaline Phosphatase (ALP)

Figure 110: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Serum Amylase

Figure 111: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Serum Lipase

Figure 112: Laboratory Results at Day 8: Mean Changes from Baseline by Laboratory Parameter and Study Arm – Creatinine

APPENDIX 3. LISTINGS MOCK-UPS

LISTINGS

Listing 1: 16.1.6: Listing of Subjects Receiving Investigational Product

Subject ID	Randomized Study Arm	Product Received Study Vaccination 1	Product Received Study Vaccination 2

16.2 Database Listings by Subject

16.2.1 Discontinued Subjects

Listing 2: 16.2.1: Early Terminations or Discontinued Subjects

Study Arm	Subject ID	Category	Reason for Early Termination or Treatment Discontinuation	Study Day

16.2.2 Protocol Deviations

Listing 3: 16.2.2.1: Subject-Specific Protocol Deviations

Study Arm	Subject ID	DV Number	Deviation	Deviation Category	Study Day	Reason for Deviation	Deviation Resulted in AE?	Deviation Resulted in Subject Termination?	Deviation Affected Product Stability?	Deviation Resolution	Comments

Listing 4: 16.2.2.2: Non-Subject-Specific Protocol Deviations

Site	Start Date	Deviation	End Date	Reason for Deviation	Deviation Resulted in Subject Termination?	Deviation Affected Product Stability?	Deviation Category	Deviation Resolution	Comments

16.2.3 Subjects Excluded from the Analysis

Listing 5: 16.2.3: Subjects Excluded from Analysis Populations

Study Arm	Subject ID	Analyses in which Subject is Included	Analyses from which Subject is Excluded	Results Available?	Reason Subject Excluded
		[e.g., Safety, ITT, PP]	[e.g., Safety, ITT, PP, Day x]		
Note: "Yes" in the "Results available" column indicates that available data were removed from the analysis. "No" indicates that no data were available for inclusion in the analysis.					

16.2.4 Demographic Data

Listing 6: 16.2.4.1: Demographic Data

[Implementation Note: If a subject is multi-racial, in "Race" column, note "Multiple: (list races, separated by a comma)."]

Subject ID	Study Arm	Sex	Age at Enrollment (years)	Ethnicity	Race	BMI

Listing 7: 16.2.4.2: Pre-Existing and Concurrent Medical Conditions

[Implementation Note: "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). If ongoing, display "Ongoing" in the "Condition End Day" column]

Subject ID	Study Arm	MH Number	Medical History Term	Condition Start Day	Condition End Day	MedDRA System Organ Class	MedDRA Preferred Term

Listing 8: 16.2.4.3: Influenza Vaccination History

Subject ID	Study Arm	Vaccine Type	Month/Year Received	Vaccination Type / Subtype

16.2.5 Compliance and/or Drug Concentration Data (if available)

Not applicable for this study.

16.2.6 Individual Immunogenicity Response Data

Listing 9: 16.2.6.1: Individual Immunogenicity Response Data – Hemagglutinin Inhibition Antibody

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Strain	Titer Replicate 1	Titer Replicate 2

Listing with similar format:

Listing 10: 16.2.6.2: Individual Immunogenicity Response Data – Neuraminidase Inhibition Antibody

Listing 11: 16.2.6.3: Individual Immunogenicity Response Data – Neutralizing Antibody

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Strain	GM Titer

Listing 12: 16.2.6.4: Individual Immunogenicity Response Data - IgG Memory B Cells

Subject ID	Study Arm	Planned Time Point	Actual Study Day	# of Spot Forming Cells per million PBMC Replicate 1	# of Spot Forming Cells per million PBMC Replicate 2	# of Spot Forming Cells per million PBMC Replicate 3[a]

[a]Two or three replicates will be reported for these assays. Use dashes if replicate 3 is not provided

Listings with similar format:

Listing 13: 16.2.6.5: Individual Immunogenicity Response Data - IgM Memory B Cells

Listing 14: 16.2.6.6: Individual Immunogenicity Response Data - IgA Memory B Cells

Listing 15: 16.2.6.7: Individual Immunogenicity Response Data – T Follicular Helper Cells

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Number and percent of Tfh cells Replicate 1	Number and percent of Tfh cells Replicate 2

Listing with similar format:

Listing 16: 16.2.6.8: Individual Immunogenicity Response Data - Plasmablasts

[Implementation note: Update the last two columns names to use 'Number and Percent of Plasmablasts']

Listing 17: 16.2.6.9: Individual Immunogenicity Response Data – Non-Neutralizing Fc-effector

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Strain	Titer

Listing 18: 16.2.6.10: Individual Immunogenicity Response Data - Antibody Forensics

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Assay	Strain	Unit	Result
						EC50	
						nMFI	

Listing 19: 16.2.6.11: Individual Immunogenicity Response Data – NA ELISA

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Assay	Strain	EC50

16.2.7 Adverse Events

Listing 20: 16.2.7.1: Solicited Events – Systemic Symptoms

Subject ID	Study Arm	Post Dose Day	Assessment[a]	Symptom	Severity	Attributed to Alternate Etiology?[b]	Alternate Etiology
			MA				
			Clinic				

[a] MA = Data reported by subject on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.
[b] Grade 3 events only.
Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

Listing 21: 16.2.7.2: Solicited Events – Local Symptoms

Subject ID	Study Arm	Post Dose Day	Assessment[a]	Symptom	Severity
			MA		
			Clinic		

[a] MA = Data reported by subject 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 22: 16.2.7.3: Unsolicited Adverse Events

Adverse Event	Associated with Dose No.	No. of Days Post Associated Dose (Duration)	Severity	MAAE?	Relationship to Study Vaccination	In Not Related, Alternative Etiology	Action Taken with Study Vaccination	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Study Arm: , Subject ID: , AE Number:											
Comments:											
Study Arm: , Subject ID: , AE Number:											
Comments:											
Note: For additional details about SAEs, see Table: xx.											

16.2.8 Individual Laboratory Measurements

Listing 23: 16.2.8.1: Clinical Laboratory Results – Chemistry

[Implementation Note: These listings (for hematology and chemistry) include all laboratory results, scheduled and unscheduled. These listings are not color-coded, but the severity should be included in parentheses after the result for abnormal results, e.g., 16.2 (Mild). The "extra" fields that are completed for abnormal results are not included in this listing; they are included in the listing of abnormal laboratory results that is included in the table shells.]

Subject ID	Study Arm	Sex	Age (years)	Planned Time Point	Actual Study Day	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)	GGT (IU/L)	ALP (IU/L)	Serum Amylase (IU/L)	Serum Lipase (IU/L)	Creatinine (mg/dL)

Listing 24: 16.2.8.2: Clinical Laboratory Results – Hematology

[Implementation Note: These listings (for hematology and chemistry) include all laboratory results, scheduled and unscheduled. These listings are not color-coded, but the severity should be included in parentheses after the result for abnormal results, e.g., 16.2 (Mild). The "extra" fields that are completed for abnormal results are not included in this listing; they are included in the listing of abnormal laboratory results that is included in the table shells.]

Subject ID	Study Arm	Sex	Age (years)	Planned Time Point	Actual Study Day	White Blood Cell (103/µL)	Hemoglobin (g/dL)	Platelets (103/µL)

16.2.9 Vital Signs and Physical Exam Findings

Listing 25: 16.2.9.1: Vital Signs

[Implementation Note: This listing includes all vital sign assessments, scheduled and unscheduled. These listings are not color-coded, but the severity should be included in parentheses after the result for abnormal assessments, e.g., 100.7 (Mild).]

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Temperature (°C)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse (beats/min)

Listing 26: 16.2.9.2: Physical Exam Findings

[Implementation Note: This listing includes all physical exam findings, scheduled and unscheduled. If a subject does not have any findings upon examination, they will not be included in this listing. If reported as an AE, display "Yes" with the AE Number in parentheses, e.g., "Yes (7)".]

Subject ID	Study Arm	Planned Time Point	Actual Study Day	Body System	Abnormal Finding	Reported as an AE? (AE Description; Number)

16.2.10 Concomitant Medications

Listing 27: 16.2.10: Concomitant Medications

[Implementation Note: "Medication Start Day" and "Medication End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact study days, categorize as follows:

- > 5 years prior to enrollment
- 1-5 years prior to enrollment
- 1-12 months prior to enrollment

If ongoing, display "Ongoing" in the "Medication End Day" column. If taken for an AE or MH, display "Yes" with the AE or MH Number in parentheses, e.g., "Yes (7)".]

Subject ID	Study Arm	CM Number	Medication	Medication Start Day	Medication End Day	Indication	Taken for an AE? (AE Number)	Taken for a condition on Medical History? (MH Number)

16.2.11 Pregnancy Reports

[Implementation Note: Only include the "Pregnancy Number" column if a subject has more than 1 pregnancy. Date of Conception will be calculated based on estimated delivery date. BMI will be calculated based on pre-pregnancy height and weight. Mother's weight gain will be calculated based on pre-pregnancy weight and end of pregnancy weight. If a major congenital anomaly with previous pregnancy, display "Yes" and the text from the "specify" field, separated by a colon. If any substance use is reported, include a listing of substance use. If autopsy revealed an alternate etiology, display "Yes" and the text from the "specify" field, separated by a colon. If abnormality in product of conception, display "Yes" and the text from the "specify" field, separated by a colon.]

Listing 28: 16.2.11.1: Pregnancy Reports – Maternal Information

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

Listing 29: 16.2.11.2: Pregnancy Reports – Gravida and Para

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

[a] Preterm Birth
[b] Term Birth

Listing 30: 16.2.11.3: Pregnancy Reports – Live Birth Outcomes

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

Listing 31: 16.2.11.4: Pregnancy Reports – Still Birth Outcomes

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

Listing 32: 16.2.11.5: Pregnancy Reports – Spontaneous, Elective, or Therapeutic Abortion Outcomes

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