CLINICAL RESEARCH IN INFECTIOUS DISEASES

STATISTICAL ANALYSIS PLAN
for
DMID Protocol 17-0090

A Phase II Study to Assess the Safety, Reactogenicity and Immunogenicity of a Single Dose of 2017 A/H7N9 Inactivated Influenza Vaccine (IIV) Administered Intramuscularly with or without AS03 Adjuvant in 2013 A/H7N9 IIV Primed or A/H7 Naïve Subjects

NCT03738241

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STUDY TITLE

Protocol Number Code:	**DMID Protocol: 17-0090**
Development Phase:	Phase II
Products:	Monovalent inactivated split influenza A/H7N9/Hong Kong/125/2017 virus vaccine (2017 A/H7N9 IIV) manufactured by Sanofi Pasteur (SP) AS03 adjuvant manufactured by GlaxoSmithKline Biologicals (GSK) Phosphate buffered saline (PBS) diluent manufactured by Patheon Manufacturing Services LLC
Form/Route:	IM
Indication Studied:	Influenza A/H7N9
Sponsor:	Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health
Clinical Trial Initiation Date:	December 12, 2018
Clinical Trial Completion Date:	June 19, 2020
Date of the Analysis Plan:	January 14, 2021
Version Number:	1.0

This study was performed in compliance with Good Clinical Practice.

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LIST OF ABBREVIATIONS

AE	Adverse Event
ALT	Alanine Aminotransferase
Bili	Total Bilirubin
BP	Blood Pressure
C	Celsius
CI	Confidence Interval
Cr	Creatinine
CRF	Case Report Form
CSR	Clinical Study Report
DMID	Division of Microbiology and Infectious Diseases
DSMB	Data and Safety Monitoring Board
eCRF	Electronic Case Report Form
F	Fahrenheit
FDA	U.S. Food and Drug Administration
GMT	Geometric Mean Titer
HA	Hemagglutinin
HAI	Hemagglutination Inhibition Antibody
Hgb	Hemoglobin
ICH	International Conference on Harmonisation
IIV	Inactivated Influenza Vaccine
IM	Intramuscularly
IRB	Institutional Review Board
mcg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
mITT	Modified Intent to Treat
mL	Milliliter
N, n	Number (typically refers to subjects)
NA	Neuraminidase
Neut	Neutralizing Antibody
NIH	National Institutes of Health

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NOCMC	New Onset Chronic Medical Condition
PI	Principal Investigator
PIMMC	Potential Immune Mediated Medical Condition
PLT	Platelets
PP	Per Protocol
PT	Preferred Term
RCD	Reverse Cumulative Distribution
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDCC	Statistical and Data Coordinating Center
SMC	Safety Monitoring Committee
SOC	System Organ Class
SOP	Standard Operating Procedures
TFLs	Tables, Figures, and Listings
WBC	White Blood Cell
WHO	World Health Organization

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1. PREFACE

This Statistical Analysis Plan (SAP) for DMID Protocol 17-0090, "A Phase II Study to Assess the Safety, Reactogenicity and Immunogenicity of a Single Dose of 2017 A/H7N9 Inactivated Influenza Vaccine (IIV) Administered Intramuscularly with or without AS03 Adjuvant in 2013 A/H7N9 IIV Primed or A/H7 Naïve Subjects," describes and expands upon the statistical information presented in the protocol.

This document describes all planned analyses and provides reasons and justifications for these analyses. It also includes sample tables, figures, and listings (TFLs) planned for final analyses included in 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 this 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 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.

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2. INTRODUCTION

Since March of 2013 [1], avian influenza A/H7N9 viruses have continued to circulate in China causing discrete outbreaks (or waves) in humans with high mortality over the past 5 years. By late 2016, a fifth wave of outbreaks was identified in China and as of May 18, 2017, a total of 1,463 laboratory-confirmed human infections with avian influenza A/H7N9 virus have been reported by the World Health Organization [2, 3]. Since the onset of the fifth wave of H7N9 outbreaks in October 2016, more human cases of H7N9 infection have been reported in China than any prior H7N9 epidemic wave [3]. The U.S. Department of Health and Human Services (HHS) recently assessed H7N9 influenza virus as having a significant potential to cause a pandemic, and the greatest risk of causing severe disease. As a result, HHS has supported the production of fifth wave A/H7N9 inactivated influenza 9 vaccines (IIVs) for the U.S. stockpile and for an assessment of their safety and immunogenicity in clinical trials.

The goal of this clinical trial is to assess in healthy adults with varying degrees of exposure to the 2013 A/H7N9 IIV, the safety, reactogenicity, and immunogenicity of one dose of a monovalent inactivated influenza A/H7N9 virus vaccine administered IM with or without AS03 adjuvant. Subjects may have been vaccinated with the 2013 A/H7N9 IIV with or without AS03 or MF59 adjuvant or may be A/H7 naïve.

2.1. Purpose of the Analyses

These analyses will assess the safety and immunogenicity of a single dose of 2017 A/H7N9 IIV administered IM with or without AS03 adjuvant in 2013 A/H7N9 IIV primed or A/H7 IIV naïve subjects and will be included in the CSR.

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3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives

3.1.1. Primary

Safety:

- To assess the safety and reactogenicity of 2017 A/H7N9 IIV given with or without AS03 adjuvant following receipt of one dose of study vaccine.

Immunogenicity:

- To assess the serum hemagglutination inhibition (HAI) and neutralizing (Neut) antibody responses following receipt of the study vaccine.

3.1.2. Secondary

Safety:

- To assess unsolicited non-serious adverse events (AEs) following receipt of the study vaccine.
- To assess medically attended adverse events (MAAEs), including new-onset chronic medical conditions (NOCMCs) and potentially immune-mediated medical conditions (PIMMCs), following receipt of the study vaccine.

Immunogenicity:

- To assess the kinetics and durability of serum HAI and Neut antibody responses following receipt of the study vaccine.

3.1.3. Exploratory

Immunogenicity:

- To assess the effects of age, sex, body mass index (BMI), and prior receipt of seasonal or non-study pandemic influenza vaccine(s) on serum HAI and Neut antibody responses following receipt of the study vaccine.
- To determine, in at least a subset of samples, the serum antibody responses to N9 neuraminidase (NA).
- To assess, in at least a subset of samples, hemaggluttinin (HA) stem-specific antibody responses.
- To assess, in at least a subset of samples, the cross-reactivity of serum HAI and Neut antibody responses to antigenically drifted variants of influenza A/H7 viruses.

3.2. Endpoints

3.2.1. Primary

Safety

- Occurrence of all serious adverse events (SAEs) from the time of study vaccination through approximately 12 months after study vaccination.

- Occurrence of solicited injection site and systemic reactogenicity events from the time of study vaccination through 7 days after study vaccination.
- Occurrence of clinical safety laboratory AEs from the time of study vaccination through approximately 7 days after study vaccination.

Immunogenicity:

- For HAI and Neut antibodies, percentage of subjects achieving seroconversion against the 2017 influenza A/H7N9 study vaccine virus (defined as either a pre-vaccination titer <10 and a post-vaccination titer ≥40 or a pre-vaccination titer ≥10 and a minimum four-fold rise in post-vaccination antibody titer) approximately 21 days after study vaccination.
- For HAI and Neut antibodies, percentage of subjects achieving titer ≥40 against the 2017 influenza A/H7N9 study vaccine virus approximately 21 days after study vaccination.
- Geometric mean titers (GMTs) of serum HAI and Neut antibodies against the 2017 influenza A/H7N9 study vaccine virus approximately 21 days after study vaccination.

3.2.2. Secondary

Safety:

- Occurrence of all unsolicited non-serious AEs from the time of study vaccination through approximately 21 days after study vaccination.
- Occurrence of all MAAEs, including NOCMCs and PIMMCs from the time of study vaccination through approximately 12 months after study vaccination.

Immunogenicity:

- For HAI and Neut antibodies, percentage of subjects seroconverting against the 2017 influenza A/H7N9 study vaccine virus approximately 7 and 180 days after study vaccination.
- For HAI and Neut antibodies, percentage of subjects achieving a titer ≥40 against the 2017 influenza A/H7N9 study vaccine virus approximately 7 and 180 days after study vaccination.
- GMTs of serum HAI and Neut antibodies against the 2017 influenza A/H7N9 study vaccine virus approximately 7 and 180 days after study vaccination.
- The percentage of subjects seroconverting, the percentage of subjects achieving a titer ≥40, and the GMTs of serum HAI and Neut antibodies against the 2013 influenza A/H7N9 vaccine virus (priming vaccine virus) approximately 21 days after study vaccination.

3.2.3. Exploratory

Immunogenicity:

- For HAI and Neut antibodies, GMTs and percentage of subjects seroconverting against the 2017 influenza A/H7N9 study vaccine virus approximately 21 days after study vaccination by age, sex, BMI, the inclusion of an adjuvant in the prime and/or boost regimens, and prior receipt of seasonal or non-study pandemic influenza vaccine(s).
- GMTs and percentage of subjects seroconverting (defined as four-fold change from baseline) of serum anti-NA (by enzyme-linked immunosorbent assay [ELISA]) or anti-neuraminidase

inhibition (NAI) (by enzyme-linked lectin assay [ELLA]) antibodies immediately prior to and 7, 21, and 180 days after study vaccination.

- Correlation between the inclusion of an adjuvant in the prime and/or boost regimens with the elicited H7 HA and N9 NA-specific serum antibody titers approximately 21 days after study vaccination.
- GMTs of HA stem-specific antibody immediately prior to and approximately 7, 21, and 180 days after study vaccination.
- For HAI and Neut antibodies, GMTs and percentage of subjects seroconverting against antigenically drifted variants of influenza A/H7 viruses approximately 21 days after study vaccination.

3.3. Study Definitions and Derived Variables

Individual subject titers are calculated by taking the geometric mean of two replicate results at each time point.

For individual subjects, fold rise will be calculated as the ratio of: $\frac{post-vaccination\ titer}{pre-vaccination\ titer}$ where pre-vaccination value is always the result obtained at Day 1, prior to the priming vaccination.

Seroconversion for HAI and Neut assays is defined as either a pre-vaccination titer <10 and a post-vaccination titer ≥40, or a pre-vaccination titer ≥10 and a minimum four-fold rise in post-vaccination titer [5].

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4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

This is a Phase II clinical trial in up to 420 males and non-pregnant females, 19 to 70 years of age, inclusive, who are in good health and meet all eligibility criteria, which include a screening erythrocyte sedimentation rate (ESR) laboratory evaluation. This clinical trial is designed to assess the safety, reactogenicity and immunogenicity of one dose of a monovalent inactivated split influenza 2017 A/H7N9 virus vaccine (2017 A/H7N9 IIV) manufactured by Sanofi Pasteur (SP), administered intramuscularly (IM) at 3.75 mcg hemagglutinin (HA) per dose, given with or without AS03 adjuvant manufactured by GlaxoSmithKline Biologicals (GSK), to subjects primed with a monovalent inactivated split influenza 2013 A/H7N9 virus vaccine (2013 A/H7N9IIV) in DMID Protocols 13-0032 and 13-0033, or to those who are A/H7 IIV-naïve. Phosphate buffered saline (PBS) diluent manufactured by Patheon Manufacturing Services LLC will be used to achieve the targeted dosage.

Subjects who received the 2013 A/H7N9 IIV in DMID Protocols 13-0032 and 13-0033 or are A/H7 IIV-naïve will be stratified by prior receipt of 2013 A/H7N9 IIV, as well as by site and 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 versus none), then randomly assigned in a 1:1 ratio to 1 of 2 treatment arms to receive 1 dose of 2017 A/H7N9 IIV at 3.75 mcg HA per dose with or without AS03 adjuvant (see Table 1).

Reactogenicity will be measured by the occurrence of solicited injection site and systemic reactions from the time of study vaccination through 7 days after study vaccination. Unsolicited non-serious adverse events (AEs) will be collected from the time of study vaccination through approximately 21 days after study vaccination. SAEs, MAAEs, including NOCMCs and PIMMCs will be collected from the time of study vaccination through approximately 12 months after study vaccination. Clinical safety laboratory evaluations (hematology and chemistry) will be performed on venous blood collected immediately prior to study vaccination and approximately 7 days after study vaccination.

Immunogenicity testing will include performing serological assays to assess hemagglutination inhibition (HAI), neutralizing (Neut), neuraminidase inhibition (NAI), neuraminidase (NA)-specific, and HA stem-specific antibody titers at multiple time points following study vaccination. Venous blood will also be collected at multiple time points following study vaccination for the future research use of serum, plasma and peripheral blood mononuclear cells (PBMCs).

Correlation of the H7 HA and N9 NA-specific serum antibody responses to the inclusion of an adjuvant in the prime and/or boost regimens will also be determined.

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 (A/H7N9) at the same dose administered with or without AS03 adjuvant.

4.3. Selection of Study Population

This study was designed to enroll up to 420 2013 A/H7N9 IIV-primed – administered with or without AS03 or MF59 - and A/H7 naïve males and non-pregnant females, 19 to 70 years of age, inclusive. 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.

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4.4. Treatments

4.4.1. Treatments Administered

Influenza A/H7N9 vaccine, AS03 adjuvant, and PBS diluent 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 Treatment Groups (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 prior receipt of 2013 A/H7N9 IIV with or without adjuvants, clinical site, and prior receipt of licensed, seasonal influenza vaccine then randomly assigned with allocation (1:1) to one of two treatment arms to receive 1 dose of 2017 A/H7N9 IIV at 3.75 mcg HA per dose with or without AS03 adjuvant. There is a total of ten strata with maximum enrollments outlined in Table 1.

4.4.4. Selection of Doses in the Study

Participants in this study are to receive one A/H7N9 vaccination at 3.75 mcg HA per dose with or without AS03 adjuvant. The 3.75 mcg dose is selected to evaluate the safety and immunogenicity of antigen sparing dose strategies after A/H7N9 prime.

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 receipt of adjuvant for the study vaccination administered on Day 1. Study groups are defined by a combination of prior receipt of 2013 A/H7N9 IIV and study product randomization as shown in Table 1.

4.4.6. Blinding

This trial is double-blinded; subjects, investigators, and study personnel performing any study-related assessments following study vaccine administration are blinded to adjuvant status. Laboratory personnel performing antibody assays are blinded to adjuvant status, subject ID, and visit number.

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 would 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 study vaccination or early termination (if prior to 21 days after study vaccination) will be solicited from the

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participant during screening, enrollment, and follow-up. Any reported prior therapies from up to 30 days prior to vaccination through 21 days post final vaccination will be recorded in the appropriate data collection form. In addition, receipt of any non-study influenza vaccines will be solicited through approximately 180 days after study vaccination and reported in the eCRF. Use of a new medication should prompt evaluation for the occurrence of any MAAE, including a new diagnosis of chronic medical disease or condition.

Prior receipt of a licensed seasonal influenza vaccine over the current (2018-2019) and previous season (2017-2018) is not exclusionary as long as it has been administered within the allowable window (protocol Section 5.1.2).

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 are to receive a single dose of study product administered in the clinic.

4.5. Efficacy (Immunogenicity) and Safety Variables

See Table 2 and Table 3 for schedules of study procedures.

4.5.1. Safety Variables

Safety will be assessed by the frequency and severity:

1. SAEs occurring from the time of study vaccination through approximately 12 months after study vaccination.
2. Solicited AEs – reactogenicity events occurring from the time of study vaccination through 7 days after study vaccination:
    a. Injection site reactions including pruritus, ecchymosis, erythema, induration/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 study vaccination through approximately 7 days after study vaccination. Parameters to be evaluated include white blood cell (WBC) count, hemoglobin (Hgb), platelets (PLT), alanine aminotransferase (ALT), total bilirubin (Bili), and creatinine (Cr).
4. Vital sign AEs occurring from the time of study vaccination through approximately 7 days after study vaccination. Parameters to be evaluated include pulse, systolic and diastolic blood pressures, and oral temperature.
5. Unsolicited AEs – non-serious AEs occurring from the time of study vaccination through approximately 21 days after study vaccination.
6. MAAEs, including NOCMCs and PIMMCs, occurring from the time of study vaccination through approximately 12 months after study vaccination.

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Grading scales for injection site and systemic solicited reactions, vital signs, and clinical laboratory parameters are provided in Table 9, Table 10, Table 11, and Table 12.

For each unsolicited AE experienced, the subject will be asked if he/she had received medical attention, defined as hospitalization, an emergency room visit or an otherwise unscheduled visit to or from medical personnel for any reason. AEs characterized by such unscheduled medical care will be designated as MAAEs.

NOCMCs are defined as any new ICD-10 diagnosis (10th revision of the International Statistical Classification of Diseases and Related Health Problems) that is applied to the subject during the course of the study, after receipt of the study agent, that is expected to continue for at least 3 months and requires continued health care intervention.

PIMMCs constitute a group of AEs that includes diseases which are clearly autoimmune in etiology and other inflammatory and/or neurologic disorders which may or may not have autoimmune etiologies. For a list of PIMMCs currently if effect, refer to protocol Appendix B.

4.5.2. Immunogenicity Variables

Individual HAI and Neut results will be reported by the central immunology laboratory for the homologous vaccine strain, A/Hong Kong/125/2017 (H7N9) and heterologous H7N9 strains, A/Shanghai/2/2013 and A/Guangdong/17SF003/2016. 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 and Neut assays is 10, values below the lower limit of detection are imputed for analysis as one-half the limit of detection (10/2 = 5). For analysis, 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 3.3 for definitions of derived variables for the analysis of HAI and Neut data.

An addendum to the SAP will be generated to outline the planned analyses for NA antigen specific antibody responses and HA stem-specific antibody responses when assay development is complete, and results are available.

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

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5. SAMPLE SIZE CONSIDERATIONS

This study is planned to enroll up to 420 subjects. The majority of subjects will be recruited from the population of subjects who received the 2013 A/H7N9 IIV in DMID Protocols 13-0032 and 13-0033. The sample size for this study was selected using estimates of recruitment based on the number of subjects completing these historical protocols and by 2013 A/H7N9 IIV vaccination history. Table 4 summarizes the vaccination history in these protocols and potential enrollment into this study. 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 5 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 treatment arms (N=30, 50), in all subjects receiving adjuvant (N=210) or in the trial as a whole (N=420).

Binomial confidence intervals (CIs) are widest (have the least precision) when the response rate is 50%. Table 6 is presented to indicate the worst-case scenario for precision of observed exact (Clopper-Pearson) binomial confidence intervals.

Table 7 illustrates the minimum detectable differences in the proportion of subjects responding (e.g. attaining seroconversion or a titer ≥40) between any two treatment arms (N=30 or 50) using a two-sided Likelihood Ratio Test with alpha = 0.05. From previous experience with single dose studies, it is assumed that up to 3% of subjects will be excluded from the per protocol analysis with minimal effect on these calculations. Seroconversion rates of 10% to 90% are considered.

6. GENERAL STATISTICAL CONSIDERATIONS

6.1. General Principles

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

- Group 1: 1 or 2 doses 2013 A/H7N9 + MF59 | 2017 A/H7N9 IIV 3.75mcg + AS03
- Group 2: 1 or 2 doses 2013 A/H7N9 + MF59 | 2017 A/H7N9 IIV 3.75mcg
- Group 3: 1 or 2 doses 2013 A/H7N9 + AS03 | 2017 A/H7N9 IIV 3.75mcg + AS03
- Group 4: 1 or 2 doses 2013 A/H7N9 + AS03 | 2017 A/H7N9 IIV 3.75mcg
- Group 5: 1 or 2 doses 2013 A/H7N9 15mcg or 45mcg | 2017 A/H7N9 IIV 3.75mcg + AS03
- Group 6: 1 or 2 doses 2013 A/H7N9 15mcg or 45mcg | 2017 A/H7N9 IIV 3.75mcg
- Group 7: 2013 A/H7N9 + MF59 or AS03 then 2013 A/H7N9 15mcg | 2017 A/H7N9 3.75mcg + AS03
- Group 8: 2013 A/H7N9 + MF59 or AS03 then 2013 A/H7N9 15mcg | 2017 A/H7N9 3.75mcg
- Group 9: A/H7N9 IIV-Naïve | 2017 A/H7N9 3.75mcg + AS03
- Group 10: A/H7N9 IIV-Naïve | 2017 A/H7N9 3.75mcg

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

6.2. Timing of Analyses

6.2.1. CSR

Once the last subject completes the visit that occurs approximately at Day 366, the clinical database will be cleaned, monitored, and locked. The CSR will be completed when all safety data through Day 366 and all humoral immunogenicity data through Day 180 are completed and uploaded.

Upon receipt of humoral immunogenicity against influenza A/Hong Kong/125/2017 (H7N9), A/Shanghai/2/2013 (H7N9), and A/Guangdong/17SF003/2016 (H7N9) strains through Day 180 and subsequent non-clinical data lock, a subset of predefined “topline tables” will be generated by the SDCC concurrently with CSR generation. These tables will include summaries of safety and immunogenicity data and will represent the final analyses of primary and secondary endpoints; as such no p-value adjustment is required. These analyses may be made available to the sponsor for planning subsequent trials and to the lead PI for publication. Tables to be included in the topline set are indicated in this document with the symbol * in the title.

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

6.3. Analysis Populations

6.3.1. Safety Population

The safety population includes all subjects who received study vaccination.

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

The modified intent-to-treat (mITT) population includes all subjects who received study vaccination and contributed both pre- an at least one post-vaccination venous blood samples for immunogenicity testing (HAI and Neut antibody assays) for which valid results were reported. For analyses using the mITT population, any subject receiving a product that is different than the one they were randomized to receive will be examined and grouped on a case by case basis.

6.3.3. Per Protocol Population

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

- Data from all available visits for subjects found to be ineligible at baseline;
- Data from all visits subsequent to major protocol deviations 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 study vaccination.
- Data from any visit that occurs more than one day out of window:
    - Visit 4 data collected before 5 days or after 10 days post vaccination;
    - Visit 6 data collected before 20 days or after 29 days post vaccination;
    - Visit 10 data collected before 166 days or after 195 days post vaccination.

Analyses will be conducted using the PP population only if 10% or more of subjects are excluded from a primary or secondary analysis timepoint. For analyses using the PP population, subjects will be grouped based on study vaccination received.

6.4. Covariates and Subgroups

As a protocol defined exploratory analysis, HAI and Neut antibody response following vaccination will be summarized stratified by the following covariates: age (categorical: 19-35, 36-50, 51-70), sex (male, female), body mass index (<30, ≥30), and prior receipt of seasonal influenza vaccine(s) (receipt of 2017-2018 or 2018-2019, or receipt of neither), and these covariates will be considered in statistical modeling as described in Section 8.3. As these analyses are exploratory the study was not powered for any subgroup analyses.

6.5. Missing Data

All attempts will be made to collect all data Per-Protocol. As missing data are expected to be minimal, no imputation will be performed for missing values. Any data point that appears to be erroneous or inexplicable

based on clinical judgment will be investigated as a possible outlier. If data points are identified as outliers, sensitivity analyses will be performed to examine the impact of including or excluding the outliers. Any substantive differences in these analyses will be reported.

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.

Clinical, safety, and reactogenicity data through approximately 365 days after study vaccination will represent the primary clinical database for this trial. Once the last subject completes the visit that occurs approximately 365 days after study vaccination and all HAI and Neut results are received, a "topline" subset of the immunogenicity and safety tables will be provided to DMID on an expedited timeline. These analyses may be made available to the sponsor for planning subsequent trials and to the lead PI for publication and 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. The DSMB may also be provided with expected and observed rates of the expected AEs in an unblinded fashion and may request the 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. 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. Summaries prepared for the DSMB are defined separately in a report shell reviewed and approved by the DSMB.

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

6.6.2. Interim Immunogenicity Review

There are no planned interim analyses for this study.

6.7. Multicenter Studies

Although randomization was stratified by site, data will be pooled across all clinical sites for all analyses. Center effects are not anticipated because the sites are using 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 the A/H7N9 vaccination 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 13 will present a summary of the reasons that subjects were screened but not enrolled.

The disposition of subjects in the study will be tabulated by study group and stratum in Table 14. The table will show the total number of subjects screened, randomized, receiving the study vaccination, completing the blood draw for the primary immunogenicity endpoints, and completing the last visit.

The number and percentage of enrolled subjects excluded from each analysis population by study group and stratum are presented in Table 15. A listing of subjects excluded from each analysis population will be presented in Listing 5.

A flowchart showing the disposition of study subjects, adapted from the CONSORT Statement [4] will be included and will present the number of subjects screened, randomized, lost to follow up, and analyzed, by study group and stratum in Figure 1.

A listing of subjects who terminated early 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, study group, and stratum for all enrolled subjects in Table 8. Major deviations that will be reviewed for possible exclusion of immunogenicity results from the PP population include deviations related to eligibility/enrollment, 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.

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8. IMMUNOGENICITY EVALUATION

Analysis of all immune responses will be conducted using the PP population. In addition, primary endpoint analyses will be conducted with the mITT population. Immune responses in terms of strain-specific A/H7N9 HAI and Neut antibody titers will be summarized by study group 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 ≥40, percentage of subjects achieving seroconversion, and GMTs along with corresponding 95% CIs. Exact CIs will be presented for proportional endpoints. Summaries of primary and secondary immunogenicity endpoints are presented in Table 22, Table 23, Table 24, and Table 25.

Reverse cumulative distribution (RCD) curves will be presented for HAI and Neut antibody titers against A/Hong Kong/125/2017 (H7N9), A/Shanghai/2/2013 (H7N9), and A/Guangdong/17SF003/2016 (H7N9) strains. Plots for each assay will be generated with 4 panels (pre-vaccination, 7 days post vaccination, 21 days post vaccination, and 180 days post vaccination) and separate curves within each panel for each study group and stratum, as shown in Figure 2, Figure 3, Figure 4, Figure 5, Figure 6, Figure 7, Figure 8, and Figure 9.

HAI and Neut antibody GMTs against A/Hong Kong/125/2017 (H7N9), A/Shanghai/2/2013 (H7N9), and A/Guangdong/17SF003/2016 (H7N9) will be presented graphically with corresponding 95% CIs in Figure 10, Figure 11, Figure 12, Figure 13, Figure 14, Figure 15, Figure 16, and Figure 17.

The spearman correlation between HAI and Neut antibody titers will be calculated at each time point over all stratum and group combinations for each strain. The correlation will be depicted in scatterplots as depicted in Figure 18, Figure 19, Figure 20, and Figure 21.

Individual HAI and Neut assay results will be provided in Listing 9 and Listing 10, respectively.

8.1. Primary Immunogenicity Analysis

The primary immunogenicity endpoints of HAI and Neut seroconversion, percentage of subjects with titer ≥40, and GMTs against the homologous A/H7N9 vaccine strain 21 days after study vaccination will be summarized as described above. Regression modeling of seroconversion and log titers is planned as described in Section 8.3.2. No formal hypothesis testing is planned.

8.2. Secondary Immunogenicity Analyses

The secondary immunogenicity endpoints of HAI and Neut seroconversion, percentage of subjects with titer ≥40, and GMTs against the homologous A/H7N9 vaccine strain 7 and 180 days after study vaccination and the 2013 A/H7N9 vaccine strain 21 days after study vaccination will be summarized as described above.

8.3. Exploratory Immunogenicity Analyses

Immunogenicity data summaries and analysis for exploratory endpoints will be presented for the PP populations.

8.3.1. Covariate Analysis

As an exploratory analysis, seroconversion and GMT of HAI and Neut antibodies against A/Hong Kong/125/2017 (H7N9) at 21 days post study vaccination will be summarized by study group, and stratified by prior receipt of 2013 A/H7N9 influenza vaccine in Table 26 and Table 27; by stratum and age (categorized as those subjects ages 19-35, 35-50, 51-70) in Table 28 and Table 29; by sex in Table 30 and Table 31; by

stratum and BMI in Table 32 and Table 33; and by stratum and prior receipt of seasonal influenza vaccines in Table 34 and Table 35.

8.3.2. Regression Modeling

Logistic and multivariable linear regression will be utilized to test for the effects of prior vaccination with 2013 A/H7N9 IIV and the addition of AS03 adjuvant to 2017 A/H7N9 IIV on seroconversion and GMT at 21 days post vaccination, respectively, for the PP population. Similar models will be fit for both HAI and Neut antibody results.

Logistic regression will be fit to examine the relationship of HAI seroconversion at 21 days post vaccination with study group, stratum, and the interaction of study group and stratum. If the available titer data meets the required assumptions of normality after log transformation, multiple linear regression will be fit to examine the relationship of log transformed titers at 21 days post vaccination with study group, stratum, and the interaction of study group and stratum. Both models will be fit with and without adjustment for the following covariates (Z): sex (female, male), age (19-35 years, 35-50 years, 51-70 years), BMI (<30, ≥30), and prior receipt of seasonal influenza vaccine (none in past 2 seasons, at least one in past 2 seasons). Modeling assumptions will be checked using standard diagnostic methods (e.g., using the INFLUENCE option in PROC LOGISTIC or PROC GLM). Parameter estimates and odds ratio estimates for the logistic models will be presented in Table 36, Table 37, Table 38, and Table 39. Parameter estimates for the multiple linear regression models will be presented in Table 40, Table 41, Table 42, and Table 43.

Model 1A: Logistic Regression (without covariate adjustment):

$$logit[P(seroconversion)] = \beta_0 + \beta_1 \times Study\ Group + \beta_2 \times Stratum + \beta_3 \times Study\ Group * Stratum$$

Model 1B: Logistic Regression (with covariate adjustment):

$$logit[P(seroconversion)] = \beta_0 + \beta_1 \times Study\ Group + \beta_2 \times Stratum + \beta_3 \times Study\ Group * Stratum + \beta_4 \times Z$$

Model 2A: Multiple Linear Regression (without covariate adjustment):

$$log(titer) = \beta_0 + \beta_1 \times Study\ Group + \beta_2 \times Stratum + \beta_3 \times Study\ Group * Stratum + \varepsilon$$

Model 2B: Multiple Linear Regression (with covariate adjustment):

$$log(titer) = \beta_0 + \beta_1 \times Study\ Group + \beta_2 \times Stratum + \beta_3 \times Study\ Group * Stratum + \beta_4 \times Z + \varepsilon$$

Subjects missing data for one or more covariates will be excluded from Models 1B and 2B.

8.3.3. Analysis of Heterologous Strains

HAI and Neut antibody responses against antigenically drifted variants of influenza A/H7 viruses, A/Shanghai/2/2013 and A/Guangdong/17SF003/2016, will be summarized for the Per Protocol population as described in Section 8. Results will be presented in Table 44 and Table 45 for A/Shanghai/2/2013 and in Table 46 and Table 47 for A/Guangdong/17F003/2016.A scatter plot of the correlation between response to the vaccine strain and each heterologous strain will be presented in Figure 23, Figure 24, Figure 25, and Figure 26. No formal hypothesis testing or modeling for the exploratory analysis of heterologous strains is planned.

8.3.4. NA Serum Antibody Responses

Descriptions of the NA assays and planned analyses will be described in an addendum to this SAP.

9. SAFETY EVALUATION

All summaries and analysis of safety data will be presented for the safety population. Safety summaries will be presented overall and grouped by study group and stratum.

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. 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 in Table 17 and Table 18 and by study group and stratum in Table 19 and Table 20. Age will be summarized as a continuous variable as well as by categories as defined in Section 8.3.1. Ethnicity is categorized as Hispanic or Latino, or not Hispanic or 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 continuous as well as categorical, categorized as (<30, ≥30). Self-reported history of prior receipt of seasonal influenza vaccine will be categorized as follows: both 2017-2018 and 2018-2019, 2017-2018 only, 2018-2019 only, receipt of none, or unknown. Demographic information for individual subjects will be provided in Listing 6.

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 group and stratum in Table 21.

Individual subject listings will be presented for all reported medical history including prior and concurrent medical conditions in 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, study group, and stratum for the safety population in Table 85. A listing of concomitant medications will be presented in Listing 18.

9.2. Measurements of Treatment Compliance

All subjects who were enrolled but not vaccinated will be presented by study group and stratum as part of the subject disposition in Table 14. Subjects receiving investigational product will be presented by site, stratum, and study group in Table 16. Listing 1 presents subjects who received investigational product with randomized study group, study product received, and stratum.

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9.3. Adverse Events

A summary of all adverse events is provided in Table 48. A summary of those events that occurred in ≥5% if subjects in any study group and stratum combination is provided in Table 49.

9.3.1. Solicited Events and Symptoms

Systemic solicited adverse events will be collected pre-vaccination and systemic and injection site solicited adverse events will be collected approximately 20 minutes post-vaccination and then daily for 7 days after study vaccination. Systemic events include fever, feverishness, fatigue, malaise, myalgia, arthralgia, headache and nausea and the grading scale for systemic events, including quantitative grading for fever is found in Table 10. Injection site events include injection site pruritus, injection site ecchymosis, injection site erythema, injection site induration/swelling, injection site pain and injection site tenderness. Ecchymosis, erythema and induration at the injection site are evaluated using both functional grade and measurement grading scales as defined in Table 9.

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

The number and percentage of subjects reporting at least one solicited adverse event of any severity will be summarized for each solicited symptom, any systemic symptom, any injection site symptom and any symptom. For each event, the denominator is the number of subjects who received the study vaccination with non-missing data for the specified event. The 95% CI calculated using Clopper-Pearson methodology from a binomial distribution (SAS Proc Freq with a binomial option) will be presented in Table 50.

For each systemic event, each local event, any systemic event, any injection site event, and any solicited event, the maximum severity over 7 days after 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, study group, and stratum. For each event the denominator is the number of subjects who received the 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 in Table 51.

The number of subjects reporting a solicited adverse event will be summarized for each day post vaccination as a summary in Table 52 and graphically in a bar chart in Figure 26 for systemic symptoms and Figure 27 for local symptoms.

Systemic and injection site solicited events reported by subject will be presented in Listing 11 and Listing 12, sorted by subject ID, 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 for these summaries will be the total number of subjects in the Safety population. All AEs reported will be included in the summaries and analyses.

The number and percentage of subjects reporting at least one unsolicited AE in each stratum and study group will be summarized by MedDRA system organ class (SOC) and preferred term (PT). A 95% CI will be

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presented for the percentage of subjects reporting any unsolicited event (serious or non-serious) for each MedDRA SOC and PT in Table 53.

The following summaries for unsolicited AEs will be presented by MedDRA SOC, PT, study group, and stratum:

- Incidence of AEs by severity and relationship to study product in Table 54;
- Incidence of non-serious, related AEs by severity in Table 55;
- Incidence of AEs over time (Days 1-8, Days 9-22 post study vaccination) in Table 56;
- Incidence of non-serious, related AEs over time (Days 1-8, Days 9-22 post study vaccination) in Table 57 – note this table presents results for the secondary safety endpoint, "Occurrence of study vaccine-related unsolicited non-serious AEs from the time of study vaccination through approximately 21 days after study vaccination";
- Total frequency of AEs over time (Days 1-8, Days 9-22 post study vaccination) in Table 58;
- Subject listing of non-serious AEs of moderate or great severity in Table 63;
- Bar chart displaying total frequency of AEs by severity, MedDRA SOC, study group, and stratum in Figure 28;
- Bar chart displaying incidence of AEs by severity, MedDRA SOC, study group, and stratum in Figure 29;
- Bar charts displaying total frequency and incidence of AEs by relationship to study product, MedDRA SOC, study group, and stratum in Figure 30 and Figure 31, respectively;

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, days post vaccination, reason reported as an SAE, relationship to study product, alternate etiology if not related, outcome, and duration of event in days:

- Deaths and serious adverse events in Table 59;
- Medically attended adverse events in Table 60;
- New onset chronic medical conditions in Table 61;
- Potentially immune mediated medical conditions in Table 62.

A listing of all reported AEs by subject will be presented in Listing 13, sorted by stratum, study group, 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 19, Listing 20, Listing 21, Listing 22, and Listing 23 will present any study related pregnancies and their outcomes.

9.6. Clinical Laboratory Evaluations

Clinical safety laboratory parameters (WBC, Hgb, PLT, ALT, Bili, Cr) will be collected from each subject prior to study vaccination and approximately 7 days after study vaccination. These evaluations will be performed by the central clinical laboratory. The grading scale for clinical laboratory evaluations is presented in Table 12. Clinical laboratory evaluations assessed on Day 1 prior to the study vaccination will be considered as baseline.

The distribution of laboratory results by severity, study day, study group, and stratum will be presented in Table 66, Table 67, Table 68, Table 69, Table 73, Table 74, Table 75, and Table 76. Descriptive statistics including mean, standard deviation, median, maximum and minimum values by each study day will be summarized for each parameter and for the change from baseline for each parameter in Table 70, Table 71, Table 72, Table 73, Table 77, Table 78, Table 79, and Table 80. Box plots illustrating the change from baseline for each laboratory parameter will be presented in Figure 32, Figure 33, Figure 34, Figure 35, Figure 36, and Figure 37. Subject visits with abnormal laboratory results, mild severity or greater, will be presented in Table 64 and Table 65 for chemistry and hematology parameters, respectively.

A complete listing of individual clinical laboratory results will be presented in Listing 14 and Listing 15 for chemistry and hematology, respectively, sorted by stratum, study group, subject ID, parameter, and visit.

9.7. Vital Signs and Physical Evaluations

Oral temperature, systolic blood pressure, diastolic blood pressure, and pulse will be assessed prior to study vaccination on Day 1 and these results will be considered as baseline. Additional measurements of vital signs may be taken on Day 2, Day 4, and Day 8 if indicated. The grading scale for vital sign evaluations is presented in Table 11. Summaries of vital signs by maximum severity will be tabulated for baseline and post-baseline measurements, grouped by stratum and study group and presented in Table 80, Table 81, Table 82, Table 83, and Table 84. A listing of vital signs will be presented in Listing 16.

Targeted physical examinations will be performed, if indicated, based on a subject's medical history. A listing of physical exam findings will be presented in Listing 17.

9.8. Concomitant Medications

Concomitant medications will be collected for the 30 days prior to study vaccination through 21 days after study vaccination. Concomitant medications will be coded to the ATC using the WHO Drug Dictionary. The use of prior and concomitant medications taken during the study will be recorded on the eCRFs. A by-subject listing of concomitant medications during the study will be summarized by ATC1 code, ATC2 code, stratum, and study group for the safety population in Table 85.

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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 does not include any changes from the analyses described in the protocol.

13. REFERENCES

1. Gao, R., et al., Human infection with a novel avian-origin influenza A (H7N9) virus. N Engl J Med, 2013. 368(20): p. 1888-97.
2. Analysis of recent scientific information on avian influenza A(H7N9) virus. WHO Influenza Update, 2017.
3. Human infection with avian influenza A(H7N9) virus – China: 18 May 2017. WHO Emergencies preparedness, response, 2017.
4. Drummond R. CONSORT Revised: Improving the Reporting of Randomized Clinical Trials. JAMA. 2001; 285(15):2006-2007.
5. FDA Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines (US DHHS, FDA, CBER, May 2007).

14. APPENDICES

Table, figure, and listing shells are presented in Appendices 1, 2, and 3. Tables and figures included in the topline report are indicated by *.

APPENDIX 1. TABLE MOCK-UPS

LIST OF TABLES

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9.1 Overall Study Design and Plan Description

Table 1: Study Design

2013 A/H7N9 Vaccination History Stratum	Study Group / N	Study Vaccination
2013 A/H7N9 IIV + MF59	1 / 50	2017 A/H7N9 IIV 3.75 mcg + AS03
	2 / 50	2017 A/H7N9 IIV 3.75 mcg
2013 A/H7N9 IIV + AS03	3 / 50	2017 A/H7N9 IIV 3.75 mcg + AS03
	4 / 50	2017 A/H7N9 IIV 3.75 mcg
2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	5 / 50	2017 A/H7N9 IIV 3.75 mcg + AS03
	6 / 50	2017 A/H7N9 IIV 3.75 mcg
2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	7 / 30	2017 A/H7N9 IIV 3.75 mcg + AS03
	8 / 30	2017 A/H7N9 IIV 3.75 mcg
A/H7 IIV-Naïve	9 / 30	2017 A/H7N9 IIV 3.75 mcg + AS03
	10 / 30	2017 A/H7N9 IIV 3.75 mcg

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9.5.1 Efficacy/Immunogenicity and Safety Measurements Assessed and Flow Chart

Table 2: Schedule of Study Procedures – Vaccination Period

Study Visit Number	**V00**	**V01**	**V02+**	**V03+**	**V04**	**V05+**	**V06**	**V07**[**]	**V08+**	**V09**[**]	**V10**	**V11**[**]
Study Day post study vaccination	**Screening (Optional) D-28 to -1**	**Enrollment Dose D1**	**D2+1d**	**D4+1d**	**D8-1/+2d**	**D15±1d**	**D22+7d**	**D61±7d**	**D91±14d**	**D121±14d**	**D181±14d**	**D366±14d**
Study Procedure/Evaluation												
Informed Consent[∞]	X	X[†¬]										
Demographic Information	X	X[†*]										
Eligibility Criteria	X	X[†¬1]										
Medical History[@]	X	X[†¬]	X	X	X	X	X		X		X	
Concomitant Medications[ς]	X	X[†¬]	X	X	X	X	X	X	X	X	X	
Vital Signs (Oral Temperature[%], Pulse and BP)	X	X[†$]	X[!]	X[!]	X[!]							
Height and Weight	X	X[†*]										
Physical Examination	X[2]	{X[†2*]}	{X}	{X}	{X}	{X}	{X}		{X}		{X}	
Urine or Serum Pregnancy Test	X[^]	X[†^]										
Venous Blood Collection for ESR	X[≠]	X[≠*]										
Enrollment in AdvantageEDC[SM] and Randomization		X[†]										
Venous Blood Collection for Clinical Safety Laboratory Evaluations~		X[†#]			X							
Venous Blood Collection for Serological Assays[π]		X[†]			X		X[Ψ]				X[Ψ]	
Venous Blood Collection for Future Research[?]		X[†]	X	X	X	X	X		X		X	
Pre-Administration Reactogenicity Assessments		X[†]										
Study Vaccination		X										
20-minute Evaluation After Study Vaccination		X										

Study Visit Number	V00	V01	V02+	V03+	V04	V05+	V06	V07**	V08+	V09**	V10	V11**
Study Day post study vaccination	Screening (Optional) D-28 to -1	Enrollment Dose D1	D2+1d	D4+1d	D8-1/+2d	D15±1d	D22+7d	D61±7d	D91±14d	D121±14d	D181±14d	D366±14d
Study Procedure/Evaluation												
Examine Study Vaccination Site		X	X	X	X							
Post-Administration Reactogenicity Assessments		X										
Distribute Memory Aid and Study-Related Materials		X										
Review Memory Aid			X	X	X							
AE/SAE Assessment		X[&]	X[&]	X[&]	X[&]	X	X	X[3]	X[3]	X[3]	X[3]	X[3]

\+ May be performed as phone call assessment for sites not processing blood for PBMCs isolation.

** Phone call assessment.

∞ Prior to study procedures.

¬ Review/confirm information or activity in subjects previously consented and screened.

† Prior to study vaccination.

* Not required if done at the optional screening visit.

1 Review results of ESR or clinical safety laboratory evaluations.

@ Complete medical history will be obtained by interview of subjects at the screening visit (optional) or on Day 1 prior to study vaccination, and interim medical history will be obtained by interview of subjects at follow-up clinic visits after study vaccination.

ς Concomitant medications limited to non-study influenza vaccines after Visit 06.

% Subjects must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.

$ Vital signs assessed on Day 1 prior to study vaccination will be considered as baseline.

! May be obtained if indicated.

2 At the screening visit (optional) or on Day 1 prior to study vaccination, 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, and as an assessment for signs suggestive of PIMMCs.

{} Targeted physical examination if indicated based on review of interim medical history.

^ Performed locally by the site at the screening visit (optional) or 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.

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Study Visit Number	V00	V01	V02+	V03+	V04	V05+	V06	V07**	V08+	V09**	V10	V11**
Study Day post study vaccination	Screening (Optional) D-28 to -1	Enrollment Dose D1	D2+1d	D4+1d	D8-1/+2d	D15±1d	D22+7d	D61±7d	D91±14d	D121±14d	D181±14d	D366±14d
Study Procedure/Evaluation												

≠ Performed locally by the site at the screening visit (optional) or on Day 1 prior to study vaccination. The ESR value must be confirmed as less than 30 mm per hour prior to randomization on Day 1 and administration of study vaccination.

~ Includes WBC, Hgb, PLT, ALT, T. Bili, Cr.

Clinical safety laboratory evaluations assessed on Day 1 prior to study vaccination will be considered as baseline.

π Approximately 5 mL of each venous blood sample is designated for future research.

? Specified sites will process blood for PBMCs isolation. Venous blood samples designated for future research will be drawn as indicated in the "Serological Assays$^{\pi}$" row.

Ψ Subjects who withdraw after receiving study vaccine will be encouraged to remain in this trial for follow-up safety assessments (may be conducted by phone call rather than in person) continuing through approximately 12 months after their study vaccination. These subjects will also be encouraged to provide a venous blood sample for serological assays approximately 21 and 180 days after their study vaccination, if feasible.

& Inclusive of reactogenicity assessments performed on the day of each study vaccination through 7 days after study vaccination.

3 AEs limited to SAEs and MAAEs, including NOCMCs and PIMMCs, that have occurred since the previous clinic visit or phone call.

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Table 3: Schedule of Study Procedures – Early Termination and Unscheduled Visits

Study Visit	Early Termination (if needed)	Unscheduled (if needed)
Study Procedure/Evaluation		
Interim Medical History	X	X (if indicated)
Concomitant Medications	X (if prior to 21 days study vaccination and receipt of any non-study influenza vaccines if within 180 days after study vaccination)	X (if prior to 21 days after study vaccination and receipt of any non-study influenza vaccines if within 180 days after study vaccination)
Vital Signs (Oral Temperature%, Pulse and BP)	X (may be obtained if indicated)	X (may be obtained if indicated)
Targeted Physical Examination	X (if indicated)	X (if indicated)
Venous Blood Collection for Clinical Safety Laboratory Evaluations~	X (if within 7 days after study vaccination)	X (if indicated)
Venous Blood Collection for Serological Assaysπ	X (if within 21 days after study vaccination)	X (if within 21 days after study vaccination)
Venous Blood Collection for Future Use?	X (if within 21 days after study vaccination)	X (if within 21 days after study vaccination)
Examine Study Vaccination Site	X (if within 7 days after study vaccination)	X (if within 7 days after study vaccination)
Post-Administration Reactogenicity Assessments	X (if within 7 days after study vaccination)	X (if within 7 days after study vaccination)
Review Memory Aid	X (if within 7 days after study vaccination)	X (if within 7 days after study vaccination)
AE/SAE Assessment3	X (if after 21 days after study vaccination)	X (if after 21 days after study vaccination)

% Subjects must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.

~ Includes WBC, Hgb, PLT, ALT, T. Bili, Cr.

π Approximately 5 mL of each venous blood sample is designated for future research.

? Specified sites will process blood for PBMCs isolation. Venous blood samples designated for future research will be drawn as indicated in the "Serological Assaysπ" row.

3 AEs limited to SAEs and MAAEs, including NOCMCs and PIMMCs, that have occurred since the previous clinic visit or phone call.

9.7.1 Sample Size

Table 4: Previously Primed Subjects for Potential Enrollment

17-0090 Study Strata	Dose 1	Dose 2	Completed All Visits	Able to recruit 50% Completers	Able to recruit 25% Completers
One or two doses 2013 A/H7N9 IIV with MF59	396	387	385	192	96
One or two doses 2013 A/H7N9 IIV with AS03	291	278	279	137	70
One or two doses 2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	396	383	383	191	95
2013 A/H7N9 IIV + MF59 or AS03 (1st) then 2013 A/H7N9 IIV 15 mcg (2nd)	199	190	193	96	48

Table 5: Power (%) to Detect Safety Events

Event Frequency	N=30	N=50	N=210	N=420
≥10% Very Common	95	>99	>99	>99
≥1% Common	26	39	87	98
≥0.1% Uncommon	2	4	18	34
≥0.01% Rare	<1	<1	2	4

Table 6: Precision of Binomial Confidence Intervals

N	95% CI
30	31-69
50	35-65
210	43-57
420	45-55

Table 7: Minimum Detectable Difference in Proportion Responders

		80% Power	
N per Treatment Arm	Proportion Responders in Comparator Group A	Minimal Detectable Difference	Proportion Responders in Comparator Group B
N=30	0.10	0.29	0.39
	0.20	0.34	0.54
	0.30	0.35	0.65
	0.40	0.35	0.75
	0.50	0.33	0.83
	0.60	0.30	0.90
	0.70	0.25	0.95
	0.80	0.19	0.99
	0.90	0.10	>0.99
N=50	0.10	0.22	0.32
	0.20	0.26	0.46
	0.30	0.27	0.57
	0.40	0.27	0.67
	0.50	0.27	0.77
	0.60	0.25	0.85
	0.70	0.22	0.92
	0.80	0.17	0.96
	0.90	0.10	>0.99

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10.2 Protocol Deviations

Table 8: Distribution of Protocol Deviations by Category, Type, and Stratum, All Enrolled Subjects

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
Category	**Deviation Type**	**# 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.**	**# 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																								

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Category	Deviation Type	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (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.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
	Delayed treatment administration																								
	Other																								
Follow-up visit schedule	Any type																								
	Out of window visit																								
	Missed visit/visit not conducted																								
	Other																								
Protocol procedure/ assessment	Any type																								
	Incorrect version of ICF signed																								
	Blood not collected																								
	Too few aliquots obtained																								
	Specimen result not obtained																								

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
Category	**Deviation Type**	# 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.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
	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																								
	Other																								
Blinding policy/procedure	Any type																								

Category	Deviation Type	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (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.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.	# of Subj.	# of Dev.
	Treatment unblinded																								
	Other																								

Notes: N = Number of subjects enrolled in given stratum; N* = Number of subjects enrolled in given stratum and study group.

12.2.2 Displays of Adverse Events

Table 9: Solicited Adverse Event Grading Scale – Injection Site

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 – hurts only when injection site is touched, or the arm is moved	The area immediately surrounding the injection site hurts only when touched or with arm motion, **and** it does **not** interfere with daily activity	The area immediately surrounding the injection site hurts when touched or with arm motion, **and** it interferes with daily activity	The area immediately surrounding the injection site hurts when touched or with arm motion, **and** it prevents daily activity
Pruritus (Itching)	Does not interfere with daily activity	Interferes with daily activity	Prevents daily activity
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 (Grade 1)**	**Medium (Grade 2)**	**Large (Grade 3)**
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

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Table 10: Solicited Adverse Event Grading Scale – Systemic

Systemic (Subjective)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Feverishness (Chills/Shivering/Sweating)	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Fatigue (Tiredness)	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Malaise (General Unwell Feeling)	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Myalgia (Body Aches/Muscular Pain)[a]	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Arthralgia (Joint Pain)[a]	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
Nausea	No interference with daily activity	Some interference with daily activity	Significant interference, prevents daily activity
Quantitative Systemic Reactogenicity Grading			
Systemic (Quantitative)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
Fever[b] – oral[c]	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

[a] Not at injection site.

[b] A fever can be considered not related to the study product if an alternative etiology can be documented. Oral temperature assessed on Day 1 prior to study vaccination will be considered as baseline.

[c] Subjects must not eat or drink anything hot or cold, or smoke within 10 minutes prior to taking oral temperature.

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Table 11: Vital Signs Adverse Event Grading

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	151 – 155	156 – 160	>160
Hypertension (diastolic) mmHg	96 – 100	101 – 105	>105

12.4.1 Individual Laboratory Measurements and Abnormal Laboratory Values

Table 12: Laboratory Adverse Event Grading Scale

Hematology	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**
WBC 10^3/µL (Decrease)	2.5 – 3.9	1.5 – 2.4	<1.5
WBC 10^3/µL (Increase)	10.6 – 15.0	15.1 – 20.0	>20.0
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/µL (Decrease)	125 – 139	100 – 124	<100
Platelets 10^3/µL (Increase)	416 – 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
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
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 13: 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	x
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

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

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Table 14: Subject Disposition by Stratum and Study Group, All Enrolled Subjects

Subject Disposition	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
	3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Screened	x	--	x	--	x	--	x	--	x	--	x	--	x	--	x	--	x	--	x	--	x	--	x	--
Enrolled/Randomized	x	100	x	100	x	100	x	100	x	100	x	100	x	100	x	100	x	100	x	100	x	100	x	100
Received Vaccination	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
Included in Per Protocol Immunogenicity Analysis of Primary Immunogenicity Outcomes[b]																								
Completed Primary Follow-up[a]																								
Completed Final Study Visit																								

Notes: N = Number of subjects enrolled in the given stratum; N* = Number of subjects enrolled in the given stratum and study group.

[a]Refer to Listing 2 for reasons subjects terminated early.

[b]Refer to Listing 5 for reasons subjects are excluded from the per protocol population.

Table 15: Analysis Populations by Stratum and Study Group, All Enrolled Subjects

Analysis Populations	Reason Subjects Excluded	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
		n	%	n	%	n	%	n	%	n	%	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	x	xx	x	xx	x	xx	x	xx	x	xx
	Study Vaccination 1 Not Received																								
Modified Intent- to- Treat	Any Reason																								
	Study Vaccination Not Received																								
	No Baseline Results Available																								
	No Post-Vaccination Results Available																								
Per-Protocol, Day 8	Any Reason																								
	Study Vaccination 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																								

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Analysis Populations	Reason Subjects Excluded	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Receipt of Immunosuppressive medication																								
	Day 8 Visit Out of Window																								
Per-Protocol, Day 15	Any Reason																								
	Study Vaccination Not Received																								
	No Baseline Results Available																								
	No Day 15 Result Reported by Lab																								
	Lost to Follow-up Before Day 15																								
	Receipt of Non-Study Vaccination																								
	Receipt of Immunosuppressive medication																								
	Day 15 Visit Out of Window																								
Per-Protocol, Day 22	Any Reason																								
	Study Vaccination Not Received																								

Analysis Populations	Reason Subjects Excluded	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	No Baseline Results Available																								
	No Day 22 Result Reported by Lab																								
	Lost to Follow-up Before Day 22																								
	Receipt of Non-Study Vaccination																								
	Receipt of Immunosuppressive medication																								
	Day 22 Visit Out of Window																								
Per-Protocol, Day 91	Any Reason																								
	Study Vaccination Not Received																								
	No Baseline Results Available																								
	No Day 91 Result Reported by Lab																								
	Lost to Follow-up Before Day 91																								
	Receipt of Non-Study Vaccination																								

Analysis Populations	Reason Subjects Excluded	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Receipt of Immunosuppressive medication																								
	Day 91 Visit Out of Window																								
Per-Protocol, Day 181	Any Reason																								
	Study Vaccination Not Received																								
	No Baseline Results Available																								
	No Day 181 Result Reported by Lab																								
	Lost to Follow-up Before Day 181																								
	Receipt of Non-Study Vaccination																								
	Receipt of Immunosuppressive medication																								
	Day 181 Visit Out of Window																								

Notes: N = Number of subjects enrolled in the given stratum; N* = Number of subjects enrolled in the given stratum and study group.

Table 16: Dates of Vaccination by Site, Stratum and Study Group, Safety Population

Dates of Dosing	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	All Subjects (N*=X)
[Site 1]																		
Total (Entire period of enrollment)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
….																		
[Site 2]																		
Total (Entire period of enrollment)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
….																		
[Repeat for all sites]																		
Notes: N = Number of subjects in the safety population in the given stratum; N* = Number of subjects in the safety population in the given stratum and study group.																		

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14.1.2 Demographic Data by Study Group

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

Variable	Characteristic	Baylor (N=X)		Cincinnati Children's (N=X)		Emory (N=X)		Kaiser Permanente (N=X)		Emory Hope Clinic (N=X)		University of Iowa (N=X)		SLU (N=X)		University of Maryland (N=X)		UTMB (N=X)		Vanderbilt (N=X)		All Subjects (N=X)	
		n	%	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	x	xx
	Female																						
BMI	< 30	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	≥ 30																						
Age	19-35 years	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	35-50 years																						
	51-70 years																						
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	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	x	xx
	Asian																						
	Native Hawaiian or Other Pacific Islander																						
	Black or African American																						

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

Variable	Characteristic	Baylor (N=X)		Cincinnati Children's (N=X)		Emory (N=X)		Kaiser Permanente (N=X)		Emory Hope Clinic (N=X)		University of Iowa (N=X)		SLU (N=X)		University of Maryland (N=X)		UTMB (N=X)		Vanderbilt (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	White																						
	Multi-Racial																						
	Unknown																						
Prior Seasonal Influenza Vaccination	2017-2018 and 2018-2019	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	2017-2018 only																						
	2018-2019 only																						
	Neither																						
	Unknown																						

Note: N = Number of subjects enrolled at the given site.

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Table 18: Summary of Continuous Demographic and Baseline Characteristics by Site

Variable	Statistic	Baylor (N=X)	Cincinnati Children's (N=X)	Emory (N=X)	Kaiser Permanente (N=X)	Emory Hope Clinic (N=X)	University of Iowa (N=X)	SLU (N=X)	University of Maryland (N=X)	UTMB (N=X)	Vanderbilt (N=X)	All Subjects (N=X)
Age	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x	x
BMI	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Minimum	x	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x	x
Note: N = Number of subjects enrolled at the given site.												

Table 19: Summary of Categorical Demographic and Baseline Characteristics by Stratum and Study Group, All Enrolled Subjects

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
Variable	**Characteristic**	**n**	**%**	**n**	**%**	**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	x	xx	x	xx
	Female																								
BMI	< 30	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	≥ 30																								
Age	19-35 years	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	35-50 years																								
	51-70 years																								
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	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	x	xx	x	xx
	Asian																								
	Native Hawaiian or Other Pacific Islander																								

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
Variable	**Characteristic**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
	Black or African American																								
	White																								
	Multi-Racial																								
	Unknown																								
Prior Seasonal Influenza Vaccination	2017-2018 and 2018-2019	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
	2017-2018 only																								
	2018-2019 only																								
	Neither																								
	Unknown																								

Notes: N = Number of subjects enrolled in the given stratum; N* = Number of subjects enrolled in the given stratum and study group.

Table 20: Summary of Continuous Demographic and Baseline Characteristics by Stratum and Study Group, All Enrolled Subjects

		2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
Variable	Statistic	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)
Age	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x	x	x	x	x
	Minimum	x	x	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x	x	x
BMI	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x	x	x	x	x	x	x	x	x	x	x	x
	Minimum	x	x	x	x	x	x	x	x	x	x	x	x
	Maximum	x	x	x	x	x	x	x	x	x	x	x	x
Notes: N = Number of subjects enrolled in the given stratum; N* = Number of subjects enrolled in the given stratum and study group.													

14.1.3 Prior and Concurrent Medical Conditions

Table 21: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class, Stratum and Study Group, Safety Population

	2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
	3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)		3.75 mcg A/H7N9 (N*=X)		3.75 mcg A/H7N9 + AS03 (N*=X)	
MedDRA System Organ Class	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any SOC	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[SOC 1]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
[SOC 2]	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx

Notes: N = Number of subjects in the safety population in the given stratum; N* = Number of subjects in the safety population in the given stratum and study group; n = number of subjects reporting medical history within the specified SOC.
A subject is only counted once per SOC.

14.2 Immunogenicity Data

14.2.1 Immune Response Against 2017 A/H7N9

Table 22: Summaries of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population*

Time Point	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)
Day 1 (Pre-Vaccination)										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
7 Days Post Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
21 Days Post Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

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Time Point	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)
GMFR (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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
180 Days Post Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Note: N = Number of subjects in the modified intent-to-treat population in the given stratum; N* = Number of subjects in the modified intent-to-treat population in the given stratum and study group; n = number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with similar format:

Table 23: Summaries of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per Protocol Population*

Table 24: Summaries of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population*

Table 25: Summaries of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per Protocol Population*

Table 26: Summary of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum and Study Group at 21 Days Post Vaccination, Per-Protocol Population*

Stratum	3.75 mcg A/H7N9 (N=X)	3.75 mcg A/H7N9 + AS03 (N=X)	All Subjects (N=X)
2013 A/H7N9 IIV + MF59			
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
2013 A/H7N9 IIV + AS03			
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted			
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)[a]			
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg			
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)[a]	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)

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Stratum	3.75 mcg A/H7N9 (N=X)	3.75 mcg A/H7N9 + AS03 (N=X)	All Subjects (N=X)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
A/H7 IIV-Naive			
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
GMFR (95% CI)[a]	xxx.x(xxx.x,xxx.x)	xxx.x(xxx.x,xxx.x)	xxx.x(xxx.x,xxx.x)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Notes: N = Number of subjects in the Per Protocol Population in the given study group; N* = Number of subjects in the Per Protocol Population in the given stratum and study group; n = number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with similar format:

Table 27: Summary of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum and Study Group at 21 Days Post Vaccination, Per-Protocol Population*

Table 28: Summary of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and Age Group at 21 Days Post Vaccination, Per-Protocol Population

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
Age 19-35 years										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Age 35-50 years										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Age 51-70 years										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

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	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
GMFR (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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Notes: N = Number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group; n = number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with similar format:

Table 29: Summary of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and Age Group at 21 Days Post Vaccination, Per-Protocol Population

Table 30: Summary of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and Sex at 21 Days Post Vaccination, Per-Protocol Population

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
Female										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Male										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Notes: N = Number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group;n = number of subjects with available results GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

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Tables with similar format:

Table 31: Summary of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Group, Stratum, and Sex at 21 Days Post Vaccination, Per-Protocol Population

Table 32: Summary of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and BMI at 21 Days Post Vaccination, Per-Protocol Population*

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
BMI < 30										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[a]	xxx.x (xxx.x,xxx.x)									
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
BMI ≥ 30										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

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	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
Notes: N = Number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group; ; n = number of subjects with available result; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise [a] Confidence Interval calculated based on the student's T distribution. [b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.										

Tables with similar format:

Table 33: Summary of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and BMI at 21 Days Post Vaccination, Per-Protocol Population*

Table 34: Summary of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and Prior Seasonal Influenza Vaccination at 21 Days Post Vaccination, Per-Protocol Population

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
Did Not Receive 2017-2018 or 2018-2019 Seasonal Influenza Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
Received 2017-2018 and/or 2018-2019 Seasonal Influenza Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

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	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)	3.75 mcg A/H7N9 + AS03 (N*=X)	3.75 mcg A/H7N9 (N*=X)
Note: N = Number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group; n = number of subjects with available result; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise. [a] Confidence Interval calculated based on the student's T distribution. [b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.										

Tables with similar format:

Table 35: Summary of Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Stratum, Study Group and Prior Seasonal Influenza Vaccination at 21 Days Post Vaccination, Per-Protocol Population

Table 36: Logistic Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with HAI Seroconversion Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Per Protocol Population

Model Parameter	Parameter Levels	Parameter Estimate	SE	p-value	Odds Ratio	95%CI
Intercept	-	xxx.x	xxx.x	x.xxx	-	-
Study Group	3.75 mcg A/H7N9 (reference)	-	-	-	-	-
	3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Stratum	A/H7 IIV-Naive (reference)	-	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + MF59	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Study Group * Stratum	A/H7 IIV-Naïve * 3.75 mcg A/H7N9 + AS03	-	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + MF59 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + AS03 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x

Note: N = XX subjects with results available at 21 days post vaccination in the per protocol population. XX subjects missing covariate data were excluded from this analysis.

P-values will be generated for study group, stratum, and the study group by stratum interaction using a likelihood-ratio test.
The p-value for the study group term was 0.xxx; The p-value for the stratum term was 0.xxx; The p-value for the study group by stratum interaction term was 0.xxx.

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Tables with similar format:

Table 37: Logistic Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Neut Seroconversion Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Per Protocol Population

Table 38: Logistic Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with HAI Seroconversion Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Adjusted for Baseline Covariates, Per Protocol Population

Model Parameter	Parameter Levels	Parameter Estimate	SE	p-value	Odds Ratio	95%CI
Intercept	-	xxx.x	xxx.x	x.xxx	-	-
Study Group	3.75 mcg A/H7N9 (reference)	-	-	-	-	-
	3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Stratum	A/H7 IIV-Naive (reference)	-	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + MF59	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Interaction: Study Group*Stratum	A/H7 IIV-Naïve * 3.75 mcg A/H7N9 + AS03	-	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + MF59 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	2013 A/H7N9 IIV + AS03 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Age	19-35 years (reference)	-	-	-	-	-
	35-50 years	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
	51-70 years	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Sex	Female (reference)	-	-	-	-	-
	Male	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
BMI Category	<30 (reference)	-	-	-	-	-

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Model Parameter	Parameter Levels	Parameter Estimate	SE	p-value	Odds Ratio	95%CI
	≥30	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Prior Receipt of Influenza Vaccine	Did Not Receive 2017-2018 or 2018-2019 Seasonal Influenza Vaccine (reference)	-	-	-	-	-
	Received 2017-2018 or 2018-2019 Seasonal Influenza Vaccine	xxx.x	xxx.x	x.xxx	xx.x	xx.x-xx.x
Note: N = XX subjects with results available at 21 days post vaccination in the per protocol population. XX subjects missing covariate data were excluded from this analysis.						

Tables with similar format:

Table 39: Logistic Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Neut Seroconversion Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Adjusted for Baseline Covariates, Per Protocol Population

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Table 40: Multiple Linear Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Log-Adjusted HAI Titer Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Per Protocol Population

Model Parameter	Parameter Levels	Parameter Estimate	SE	95% CI	p-value
Intercept	-	xxx.x	xxx.x	-	x.xxx
Study Group	3.75 mcg A/H7N9 (reference)	-	-	-	-
	3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Stratum	A/H7 IIV-Naive (reference)	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + MF59	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Interaction: Study Group*Stratum	A/H7 IIV-Naïve * 3.75 mcg A/H7N9 + AS03	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + MF59 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + AS03 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Note: N = XX subjects with results available at 21 days post vaccination in the per-protocol population. XX subjects missing covariate data were excluded from this analysis.					

Tables with similar format:

Table 41: Multiple Linear Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Log-Adjusted Neut Titer Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Per Protocol Population

Table 42: Multiple Linear Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Log-Adjusted HAI Titer Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Adjusted for Baseline Covariates, Per-Protocol Population

Model Parameter	Parameter Levels	Parameter Estimate	SE	95% CI	p-value
Intercept	-	xxx.x	xxx.x	-	x.xxx
Treatment	3.75 mcg A/H7N9 (reference)	-	-	-	-
	3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Stratum	A/H7 IIV-Naive (reference)	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + MF59	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Interaction: Study Group*Stratum	A/H7 IIV-Naïve * 3.75 mcg A/H7N9 + AS03	-	-	-	-
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + MF59 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	2013 A/H7N9 IIV + AS03 * 3.75 mcg A/H7N9 + AS03	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Age	19-35 years (reference)	-	-	-	-
	35-50 years	xxx.x	xxx.x	xx.x-xx.x	x.xxx
	51-70 years	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Sex	Female (reference)	-	-	-	-
	Male	xxx.x	xxx.x	xx.x-xx.x	x.xxx
BMI Category	<30 (reference)	-	-	-	-
	≥30	xxx.x	xxx.x	xx.x-xx.x	x.xxx

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Model Parameter	Parameter Levels	Parameter Estimate	SE	95% CI	p-value
Prior Receipt of Influenza Vaccine	Did Not Receive 2017-2018 or 2018-2019 Seasonal Influenza Vaccine (reference)	-	-	-	-
	Received 2017-2018 or 2018-2019 Seasonal Influenza Vaccine	xxx.x	xxx.x	xx.x-xx.x	x.xxx
Note: N = XX subjects with results available at 21 days post vaccination in the per-protocol population. XX subjects missing covariate data were excluded from this analysis.					

Tables with similar format:

Table 43: Multiple Linear Regression Model to Evaluate the Relationship of AS03 Adjuvant and Stratum with Log-Adjusted Neut Titer Against A/Hong Kong/125/2017 (H7N9) at 21 Days Post Study Vaccination, Adjusted for Baseline Covariates, Per Protocol Population

Table 44: Summaries of Hemagglutination Inhibition Antibody Against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
Time Point	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**
Day 1 (Pre-Vaccination)										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
21 Days Post Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Notes: N = number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group; n = number of subjects with available result; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with similar format:

Table 45: Summaries of Neutralizing Antibody Against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per Protocol Population

Table 46: Summaries of Hemagglutination Inhibition Antibody Against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per Protocol Population

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)	
Time Point	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**	**3.75 mcg A/H7N9 (N*=X)**	**3.75 mcg A/H7N9 + AS03 (N*=X)**
Day 1 (Pre-Vaccination)										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)
21 Days Post Vaccination										
n	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)
Titer ≥ 1:40 - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	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)[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)
Seroconversion - % (95% CI)[b]	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)

Notes: N = Number of subjects in the per-protocol population in the given stratum; N* = Number of subjects in the per-protocol population in the given stratum and study group; n = number of subjects with available results; GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise.

[a] Confidence Interval calculated based on the student's T distribution.

[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.

Tables with similar format:

Table 47: Summaries of Neutralizing Antibody Against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per Protocol Population

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14.3 Safety Data

14.3.1 Displays of Adverse Events

Table 48: Overall Summary of Adverse Events, Safety Population*

	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
3.75 mcg A/H7N9 IIV (N*=X)												
Subjects[a] with	n	%	n	%	n	%	n	%	n	%	n	%
At least one injection site solicited adverse event	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
At least one unsolicited adverse event	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
Mild (Grade 1)	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
Severe (Grade 3)	x	x	x	x	x	x	x	x	x	x	x	x
At least one severe (Grade 3) unsolicited adverse event	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
Unrelated	x	x	x	x	x	x	x	x	x	x	x	x
At least one serious adverse event[b]	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
At least one adverse event leading to early termination[c]	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
At least one new onset chronic medical condition	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
At least one clinical safety laboratory adverse event	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

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	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
Moderate (Grade 2)	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
3.75 mcg A/H7N9 IIV + AS03 (N*=X)												
Subjects[a] with	n	%	n	%	n	%	n	%	n	%	n	%
At least one injection site solicited adverse event	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
At least one unsolicited adverse event	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
Mild (Grade 1)	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
Severe (Grade 3)	x	x	x	x	x	x	x	x	x	x	x	x
At least one severe (Grade 3) unsolicited adverse event	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
Unrelated	x	x	x	x	x	x	x	x	x	x	x	x
At least one serious adverse event[b]	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
At least one adverse event leading to early termination[c]	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
At least one new onset chronic medical condition	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
At least one clinical safety laboratory adverse event	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
Moderate (Grade 2)	x	x	x	x	x	x	x	x	x	x	x	x

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	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
Severe (Grade 3)	x	x	x	x	x	x	x	x	x	x	x	x
At least one vital signs adverse event	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
Moderate (Grade 2)	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

Notes: N = Number of subjects in the safety population who received study vaccination in the given stratum; N* = Number of subjects in the safety population in the given study group; n = number of subjects with available results.

[a] Subjects are counted once for each category regardless of the number of events.

[b] A listing of Serious Adverse Events is included in Table 59

[c] As reported on the Adverse Event eCRF

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Table 49: Adverse Events Occurring in at least 5% of Subjects in Any Study Group by MedDRA System Organ Class and Preferred Term, Stratum and Study Group, Safety Population

Preferred Term	MedDRA System Organ Class	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			2013 A/H7N9 IIV + MF59 (N=X)		
		n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events	n	%	Events
3.75 mcg A/H7N9 IIV (N*=X)																			
Serious Adverse Events																			
All	All	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
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
PT1	SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc.	Etc.																		
Solicited Adverse Events																			
All	All	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
Etc.	Etc.																		
Clinical Safety Laboratory Adverse Events																			
All	All	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
Etc.	Etc.																		
Vital Signs Adverse Events																			
All	All	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

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Preferred Term	MedDRA System Organ Class	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			2013 A/H7N9 IIV + MF59 (N=X)		
Etc.	Etc.																		
Total																			
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3.75 mcg A/H7N9 IIV + AS03 (N*=X)																			
Serious Adverse Events																			
All	All	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
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
SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc.																			
Solicited Adverse Events																			
All	All	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
Etc.	Etc.																		
Clinical Safety Laboratory Adverse Events																			
All	All	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
Etc.	Etc.																		
Vital Signs Adverse Events																			
All	All	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

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Preferred Term	MedDRA System Organ Class	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			2013 A/H7N9 IIV + MF59 (N=X)		
Etc.	Etc.																		
Total																			
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
All Subjects (N*=X)																			
Serious Adverse Events																			
All	All	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
Etc.	Etc.																		
Other (Non-serious) Adverse Events																			
All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
SOC1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Etc.																			
Solicited Adverse Events																			
All	All	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
Etc.	Etc.																		
Clinical Safety Laboratory Adverse Events																			
All	All	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
Etc.	Etc.																		
Total																			
All	All	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

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Preferred Term	MedDRA System Organ Class	2013 A/H7N9 IIV + MF59 (N=X)	2013 A/H7N9 IIV + AS03 (N=X)	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)	A/H7 IIV Naïve (N=X)	2013 A/H7N9 IIV + MF59 (N=X)
Notes: N = number of subjects in the safety population in the given stratum; N* = number of subjects in the safety population in the given study group; n = number of subjects reporting event; Events = total frequency of events reported. MedDRA Version X.X. The preferred term "Pain injection site" identifies both injection site tenderness and injection site pain. To distinguish between the two events, the preferred term "Pain injection site (tenderness)" was used to identify injection site tenderness.							

14.3.1.1 Solicited Adverse Events

Table 50: Number and Percentage of Subjects Experiencing Solicited Events with 95% Confidence Intervals by Symptom, Stratum and Study Group, Safety Population

	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
Symptom	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**
3.75 mcg A/H7N9 IIV																		
Any Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Systemic Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fever	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Feverishness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fatigue	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Malaise	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Myalgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Arthralgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Headache	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Nausea	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Injection Site Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pain	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Tenderness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pruritus	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx

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Symptom	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Induration/Swelling	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Induration/Swelling (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
3.75 mcg A/H7N9 IIV + AS03																		
Any Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Systemic Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fever	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Feverishness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fatigue	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Malaise	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Myalgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Arthralgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Headache	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Nausea	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Injection Site Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pain	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Tenderness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pruritus	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Induration/Swelling	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx

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Symptom	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
Induration/Swelling (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
All Subjects																		
Any Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Systemic Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fever	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Feverishness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Fatigue	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Malaise	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Myalgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Arthralgia	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Headache	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Nausea	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Any Injection Site Symptom	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pain	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Tenderness	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Pruritus	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Ecchymosis (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Erythema (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Induration/Swelling	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx
Induration/Swelling (measurement)	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx	x	xx	xx, xx

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	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
Symptom	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**
Notes: N = Number of subjects in the safety population for the given stratum; n = number of subjects with reported event. 95% CI estimated using Clopper-Pearson exact method.																		

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Table 51: Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Stratum and Study Group, Safety Population

Symptom	Severity	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
3.75 mcg A/H7N9 IIV																			
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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Fever	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Feverishness	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Fatigue	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

Symptom	Severity	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Malaise	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Myalgia	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Arthralgia	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Headache	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Nausea	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Any Injection Site 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

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

Symptom	Severity	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
	Mild	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Pain	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Tenderness	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Pruritus	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Ecchymosis	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
Ecchymosis (measurement)	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	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

Symptom	Severity	2013 A/H7N9 IIV + MF59 (N=X)			2013 A/H7N9 IIV + AS03 (N=X)			2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)			2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)			A/H7 IIV Naïve (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI	n	%	95% CI
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
Erythema	None	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Mild	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
Erythema (measurement)	None	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Mild	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
Induration/Swelling	None	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Mild	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
Induration/Swelling (measurement)	None	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Mild	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Moderate	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
	Severe	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	x	xx	xx-xx	xx	xx-xx	xx-xx
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]																			

Notes: N = Number of subjects in the safety population in the given stratum; n = number of subjects with reported event.
95% CI estimated using Clopper-Pearson exact method
Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

Table 52: Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Severity, Day Post Vaccination, Stratum and Study Group, 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	%
3.75 mcg A/H7N9 (N=X)																					
All Subjects (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																				

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	%
Malaise	None																				
	Mild																				
	Moderate																				
	Severe																				
Myalgia	None																				
	Mild																				
	Moderate																				
	Severe																				
Arthralgia	None																				
	Mild																				
	Moderate																				
	Severe																				
Headache	None																				
	Mild																				
	Moderate																				
	Severe																				
Nausea	None																				
	Mild																				
	Moderate																				
	Severe																				
Any Injection Site Symptom	None																				
	Mild																				
	Moderate																				
	Severe																				
Pain	None																				

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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																				
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																				

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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																				
Induration/Swelling	None																				
	Mild																				
	Moderate																				
	Severe																				
Induration/Swelling (measurement)	None																				
	Mild																				
	Moderate																				
	Severe																				
[Repeat for Stratum 1 – 5]																					
[repeat for 3.75 mcg A/H7N9 IIV + AS03 (N=X) and All Subjects (N=X)]																					

Notes: N = Number of subjects in the safety population in the given study group; N* = Number of subjects in the safety population in the given study group and stratum; n = number of subjects with reported event.
Severity is the maximum severity reported post dosing for each subject for each day.

14.3.1.2 Unsolicited Adverse Events

Table 53: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events with 95% Confidence Intervals by MedDRA System Organ Class and Preferred Term, Stratum and Study Group, Safety Population

		2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (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)**
3.75 mcg A/H7N9 IIV													
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]												
3.75 mcg A/H7N9 IIV + AS03													
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]												
All Subjects													

		2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (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]												

Notes: N = Number of subjects in the safety population in the given stratum; n = number of subjects with reported event.
A subject is only counted once per PT.

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Table 54: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, Stratum and Study Group, Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[a]						Relationship to Vaccination[b]			
				Mild		Moderate		Severe		Not Related		Related	
		n	%	n	%	n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 (N=X)													
All Subjects (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]												
[repeat for Strata 1 - 5]													
[repeat for 3.75 mcg A/H7N9 IIV + AS03 (N=X) and All Subjects (N=X)]													

Notes: N = Number of subjects in the safety population in the given study group; N* = Number of subjects in the safety population in the given study group and stratum; n = number of subjects with reported event.

[a] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.

[b] For relationship, a subject is only counted once per preferred term and is summarized according to their closest relationship.

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Table 55: Number and Percentage of Subjects Experiencing Non-Serious Related Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Stratum and Study Group, Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	Any Incidence		Severity[a]					
				Mild		Moderate		Severe	
		n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 (N=X)									
All Subjects (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]								
[repeat for Strata 1 - 5]									
[repeat for 3.75 mcg A/H7N9 IIV + AS03 (N=X) and All Subjects (N=X)]									

Notes: N = Number of subjects in the safety population in the given study group; N* = Number of subjects in the safety population in the given study group and stratum; n = number of subjects with reported event.

[a] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.

Table 56: Number and Percentage of Subjects Experiencing Unsolicited Adverse Events Within 21 Days Post Study Vaccination by MedDRA System Organ Class and Preferred Term, Day Post Vaccination, Stratum and Study Group, Safety Population

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac	
MedDRA System Organ Class	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
3.75 mcg A/H7N9																									
Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	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]																								
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]																									

Notes: N = Number of subjects in the safety population in the given stratum; n = number of subjects with reported event.
For each time period, a subject is only counted once per PT.

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Table 57: Number and Percentage of Subjects Experiencing Non-Serious, Related Unsolicited Adverse Events Within 21 Days Post Vaccination by MedDRA System Organ Class and Preferred Term, Study Vaccination, Stratum and Study Group, Safety Population

		2013 A/H7N9 IIV + MF59 (N=X)				2013 A/H7N9 IIV + AS03 (N=X)				2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)				2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)				A/H7 IIV Naïve (N=X)				All Subjects (N=X)			
		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac		Day 1-8 Post Vac		Day 9-22 Post Vac	
MedDRA System Organ Class	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
3.75 mcg A/H7N9																									
Any SOC	Any PT	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	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]																								
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]																									

Notes: N = Number of subjects in the safety population in the given stratum; n = number of subjects with reported event.
For each time period, a subject is only counted once per PT.

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Table 58: Number of Unsolicited Adverse Events by MedDRA System Organ Class and Preferred Term, Day Post Vaccination, Stratum and Study Group, Safety Population

		2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
		Day 1-8 Post Vac	Day 9-22 Post Vac	Day 1-8 Post Vac	Day 9-22 Post Vac	Day 1-8 Post Vac	Day 9-22 Post Vac	Day 1-8 Post Vac	Day 9-22 Post Vac	Day 1-8 Post Vac	Day 9-22 Post Vac	Day 1-8 Post Vac	Day 9-22 Post Vac
MedDRA System Organ Class	**MedDRA Preferred Term**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**	**Events**
3.75 mcg A/H7N9													
Any SOC	Any PT	x	x	x	x	x	x	x	x	x	x		
[SOC 1]	Any PT												
	[PT 1]												
	[PT 2]												
[SOC 2]	Any PT												
	[PT 1]												
	[PT 2]												
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]													
Notes: N = Number of subjects in the safety population in the given stratum.													

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14.3.2 Listing of Deaths, Other Serious and Significant Adverse Events

Table 59: Listing of Serious Adverse Events, Safety Population

[Implementation Note: This listing is included in the table shells document, as it is included in the body of the CSR. 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	No. of Days Post Vac (Duration)	No. of Days Post Vac the Event Became Serious	Reason Reported as an SAE	Severity	Relationship to Study Treatment	If Not Related, Alternative Etiology	Subject Withdrew Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Study Group: , AE Number:										
Comments:										
Subject ID: , Study Group: , AE Number:										
Comments:										

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Table 60: Listing of Medically Attended Adverse Events, Safety Population

[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	No. of Days Post Vac (Duration)	Severity	Relationship to Study Treatment	If Not Related, Alternative Etiology	Subject Withdrew Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Study Group: , AE Number:								
Comments:								
Subject ID: , Study Group: , AE Number:								
Comments:								

Tables with similar format:

Table 61: Listing of New Onset Chronic Medical Conditions, Safety Population

Table 62: Listing of Potentially Immune Mediated Medical Conditions, Safety Population

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

14.3.3 Narratives of Deaths, Other Serious and Significant Adverse Events

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

14.3.4 Abnormal Laboratory Value Listings (by Subject)

Table 64: Listing of Abnormal Laboratory Results – Chemistry, Safety Population

Subject ID	Study Group	Stratum	Sex	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternate Etiology	Subject Withdrew Due to Result?

Table 65: Listing of Abnormal Laboratory Results – Hematology, Safety Population

Subject ID	Study Group	Stratum	Sex	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternate Etiology	Subject Withdrew Due to Result?

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14.3.4.5 Clinical Laboratory Reference Ranges

(Placeholder for the CSR)

14.3.5 Displays of Laboratory Results

14.3.5.1 Chemistry Results

Table 66: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – Any Chemistry Parameter, Safety Population

Study Group	Stratum	Study Day	N	None		Mild / Grade 1		Moderate/ Grade 2		Severe/ Grade 3		Missing	
				n	%	n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	X	x	xx	x	xx	x	xx	x	xx	x	xx
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV + AS03	Baseline											
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline											
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline											
		Day 8											
		Max Severity Post Baseline											
	A/H7 IIV-Naive	Baseline											
		Day 8											

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Study Group	Stratum	Study Day	N	None		Mild / Grade 1		Moderate/ Grade 2		Severe/ Grade 3		Missing	
				n	%	n	%	n	%	n	%	n	%
		Max Severity Post Baseline											
	All Subjects	Baseline											
		Day 8											
		Max Severity Post Baseline											
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]													

Note: N = Number of subjects in the safety population within the given study group and stratum with visit documentation for the corresponding day; n = number of events.
The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

Tables with similar format:

Table 67: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group - Alanine Aminotransferase, Safety Population

Table 68: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group - Total Bilirubin, Safety Population

Table 69: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – Creatinine, Safety Population

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Table 70: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – Alanine Aminotransferase (IU/L), Safety Population

Study Group	Stratum	Study Day	N	Mean	Standard Deviation	Median	Min, Max
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	x	xx.x	xx.x	xx	xx, xx
		Day 8					
	2013 A/H7N9 IIV + AS03	Baseline					
		Day 8					
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline					
		Day 8					
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline					
		Day 8					
	A/H7 IIV-Naive	Baseline					
		Day 8					
	All Subjects	Baseline					
		Day 8					
[Repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]							
Note: N = Number of subjects in the safety population.							

Tables with similar format:

Table 71: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – Total Bilirubin (mg/dL), Safety Population

Table 72: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – Creatinine, Safety Population

14.3.5.2 Hematology Results

Table 73: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – Any Hematology Parameter, Safety Population

Study Group	Stratum	Study Day	N	None		Mild / Grade 1		Moderate/ Grade 2		Severe/ Grade 3		Missing	
				n	%	n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	X	x	xx	x	xx	x	xx	x	xx	x	xx
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV + AS03	Baseline											
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline											
		Day 8											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline											
		Day 8											
		Max Severity Post Baseline											
	A/H7 IIV-Naive	Baseline											
		Day 8											
		Max Severity Post Baseline											
	All Subjects	Baseline											

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Study Group	Stratum	Study Day	N	None		Mild / Grade 1		Moderate/ Grade 2		Severe/ Grade 3		Missing	
				n	%	n	%	n	%	n	%	n	%
		Day 8											
		Max Severity Post Baseline											
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]													

Note: N = Number of subjects in the safety population within the given study group and stratum with visit documentation for the corresponding day.
The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

Table with similar format:

Table 74: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – Hemoglobin, Safety Population

Table 75: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – White Blood Cells ($10^3/\mu L$), Safety Population

Study Group	Stratum	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	%
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
		Day 8																	
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV + AS03	Baseline																	
		Day 8																	
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline																	
		Day 8																	
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline																	
		Day 8																	
		Max Severity Post Baseline																	
	A/H7 IIV-Naive	Baseline																	
		Day 8																	
		Max Severity Post Baseline																	

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Study Group	Stratum	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	%
	All Subjects	Baseline																	
		Day 8																	
		Max Severity Post Baseline																	
[repeat for 3.75 mcg A/H7N9 IIV + AS03]																			

Note: N = Number of subjects in the safety population within the given study group and stratum with visit documentation for the corresponding day.
The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

Table with similar format:

Table 76: Laboratory Results by Parameter, Maximum Severity, Study Day, Stratum and Study Group – Platelets (10^3/µL), Safety Population

Table 77: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – Hemoglobin (g/dL), Safety Population

Study Group	Stratum	Study Day	N	Mean	Standard Deviation	Median	Min, Max
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	x	xx.x	xx.x	xx	xx, xx
		Day 8					
	2013 A/H7N9 IIV + AS03	Baseline					
		Day 8					
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline					
		Day 8					
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline					
		Day 8					
	A/H7 IIV-Naive	Baseline					
		Day 8					
	All Subjects	Baseline					
		Day 8					
[Repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]							
Note: N = Number of subjects in the safety population							

Tables with similar format:

Table 78: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – White Blood Cells (10^3/µL), Safety Population

Table 79: Laboratory Summary Statistics by Parameter, Study Day, Stratum and Study Group – Platelets (10^3/µL), Safety Population

14.3.6 Displays of Vital Signs

Table 80: Vital Signs by Assessment, Maximum Severity, Study Day, Stratum and Study Group – Any Assessment, Safety Population

Study Group	Stratum	Study Day	N	None		Mild		Moderate		Severe		Missing	
				n	%	n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	X	x	xx	x	xx	x	xx	x	xx	x	xx
		Max Severity Post Baseline											
	2013 A/H7N9 IIV + AS03	Baseline											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline											
		Max Severity Post Baseline											
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline											
		Max Severity Post Baseline											
	A/H7 IIV-Naive	Baseline											
		Max Severity Post Baseline											
	All Subjects	Baseline											
		Max Severity Post Baseline											
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]													

Note: N = Number of subjects in the safety population within the given study group and stratum with visit documentation for the corresponding day.
The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

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Table with similar format:

Table 81: Vital Signs by Assessment, Maximum Severity, Study Day, Stratum and Study Group - Oral Temperature, Safety Population

Table 82: Vital Signs by Assessment, Maximum Severity, Study Day, Stratum and Study Group – Systolic Blood Pressure, Safety Population

Study Group	Stratum	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	%
3.75 mcg A/H7N9 IIV	2013 A/H7N9 IIV + MF59	Baseline	x	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx	x	xx
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV + AS03	Baseline																	
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted	Baseline																	
		Max Severity Post Baseline																	
	2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg	Baseline																	
		Max Severity Post Baseline																	
	A/H7 IIV-Naive	Baseline																	
		Max Severity Post Baseline																	
	All Subjects	Baseline																	
		Max Severity Post Baseline																	
[repeat for 3.75 mcg A/H7N9 IIV + AS03 and All Subjects]																			

Note: N = Number of subjects in the safety population within the given study group and stratum with visit documentation for the corresponding day.
The "Max Post Baseline" rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.

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Tables with similar format:

Table 83: Vital Signs by Assessment, Maximum Severity, Study Day, Stratum and Study Group - Diastolic Blood Pressure, Safety Population

Table 84: Vital Signs by Assessment, Maximum Severity, Study Day, Stratum and Study Group - Pulse, Safety Population

14.4 Summary of Concomitant Medications

Table 85: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification, Stratum and Study Group, Safety Population

WHO Drug Code Level 1, Anatomic Group	WHO Drug Code Level 2, Therapeutic Subgroup	2013 A/H7N9 IIV + MF59 (N=X)		2013 A/H7N9 IIV + AS03 (N=X)		2013 A/H7N9 IIV 15 mcg or 45 mcg unadjuvanted (N=X)		2013 A/H7N9 IIV with MF59/AS03 then 2013 A/H7N9 IIV 15 mcg (N=X)		A/H7 IIV Naïve (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%	n	%	n	%
3.75 mcg A/H7N9 IIV (N*=X)													
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]												
[repeat for 3.75 mcg A/H7N9 IIV + AS03 (N*=X) and All Subjects (N*=X)]													

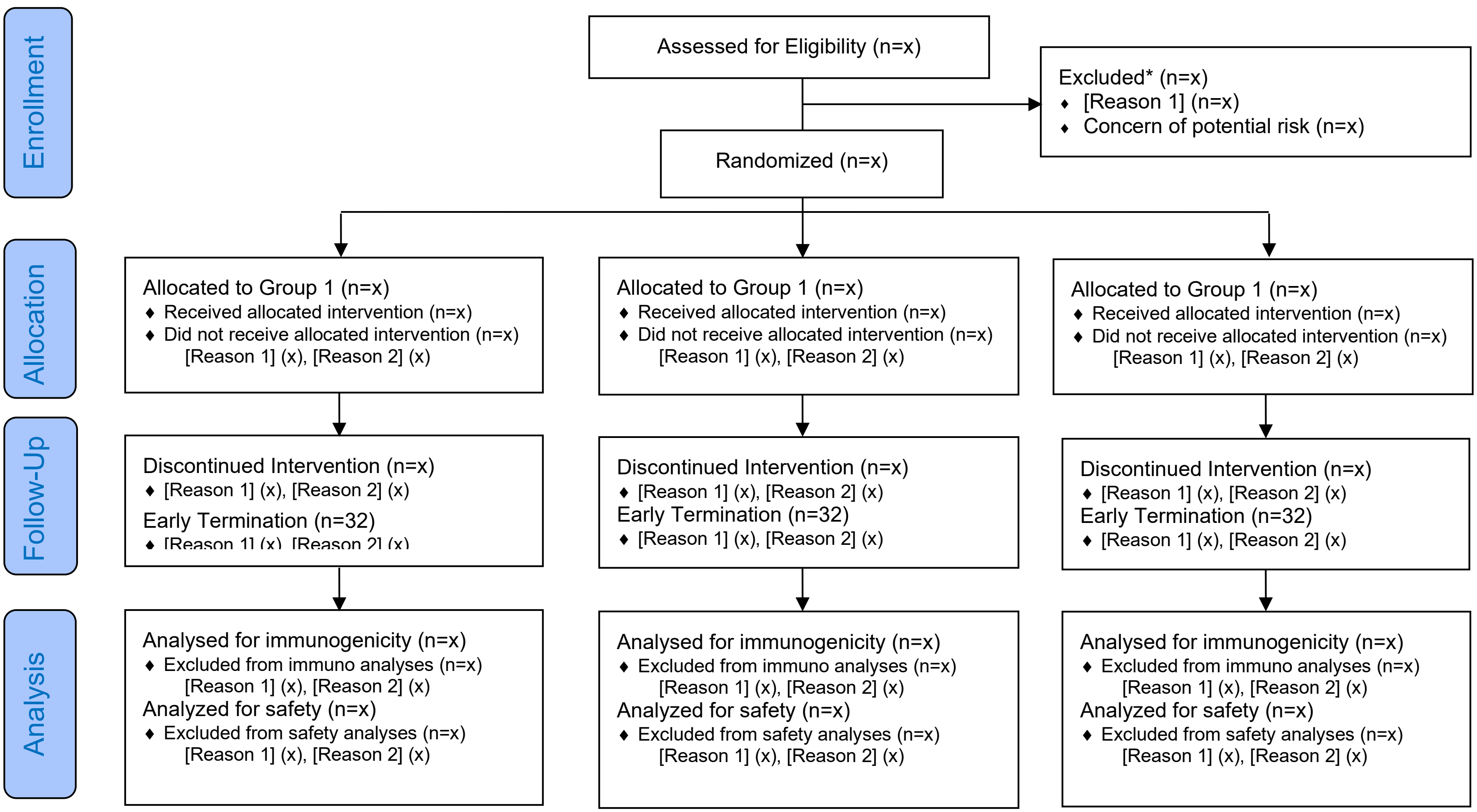
Notes: N = Number of subjects in the safety population in the given stratum; N* = Number of subjects in the safety population in the given study group; n = Number of subjects reporting taking at least one medication in the specific WHO Drug Class.

APPENDIX 2. FIGURE MOCK-UPS

LIST OF FIGURES

10.1 Disposition of Subjects

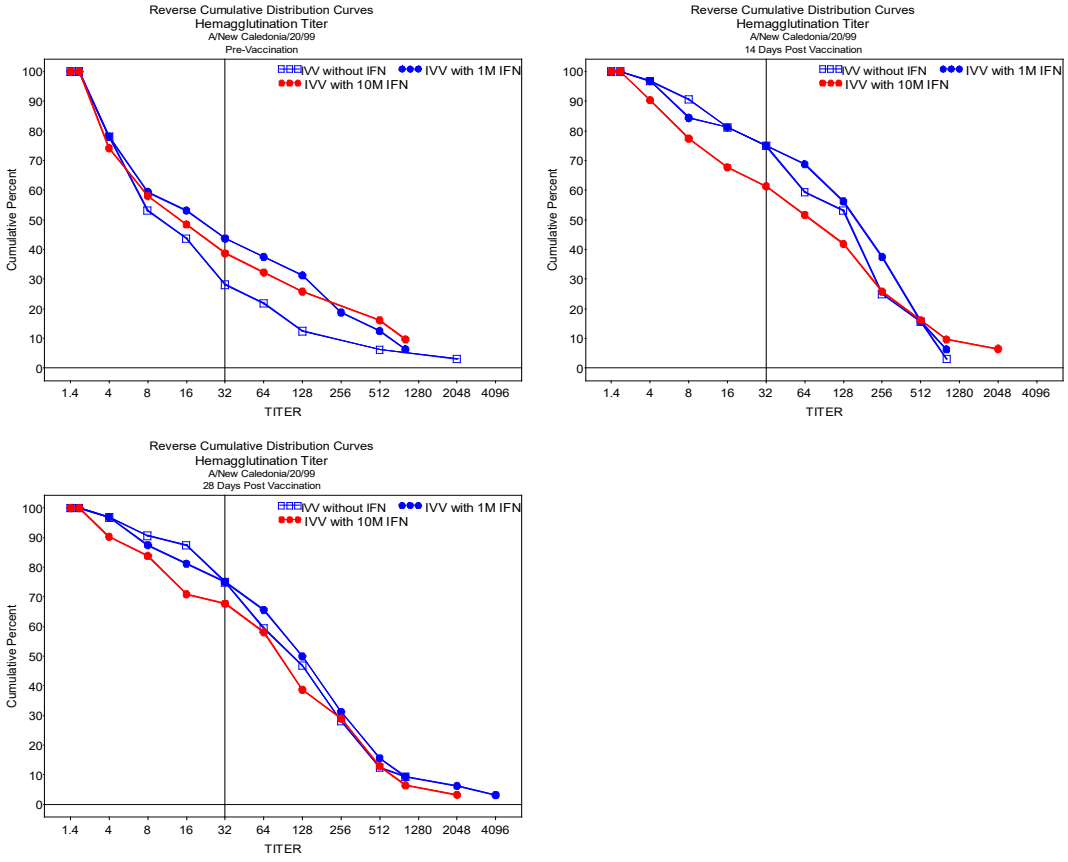
Figure 1: CONSORT Flow Diagram



14.2.2 Immunogenicity Response Figures

Figure 2: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, 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 separate panels for each study day (Day 1, Day 8, Day 22, Day 181). Figures generated for expedited interim analysis and preliminary report will include data from all available visits at the time of report generation. Visit labels should be included in the panel headers. Within each panel individual curves should be used for each treatment arm and strata within treatment arm (ten curves). Each treatment arm should be either a dashed or solid line with different color and markers used to distinguish strata.]



Figures with similar format:

Figure 3: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 4: Reverse Cumulative Distribution of Neutralizing Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population

Figure 5: Reverse Cumulative Distribution of Neutralizing Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 6: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 7: Reverse Cumulative Distribution of Neutralizing Antibody against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 8: Reverse Cumulative Distribution of Hemagglutination Inhibition Antibody against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 9: Reverse Cumulative Distribution of Neutralizing Antibody against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

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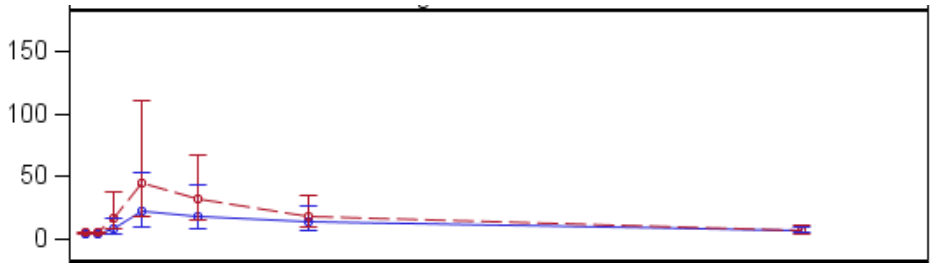
Figure 10: Geometric Mean Titers of Hemagglutination Inhibition Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population

[Implementation Note: A generic sample figure is shown below. Planned Study Day 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 treatment group with different marker shapes/colors for each treatment arm. Each treatment arm should have open/closed markers and dashed/solid lines, with separate color and marker shape used to distinguish strata]



Figures with similar format:

Figure 11: Geometric Mean Titers of Hemagglutination Inhibition Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 12: Geometric Mean Titers of Neutralizing Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population

Figure 13: Geometric Mean Titers of Neutralizing Antibody against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 14: Geometric Mean Titers of Hemagglutination Inhibition Antibody against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

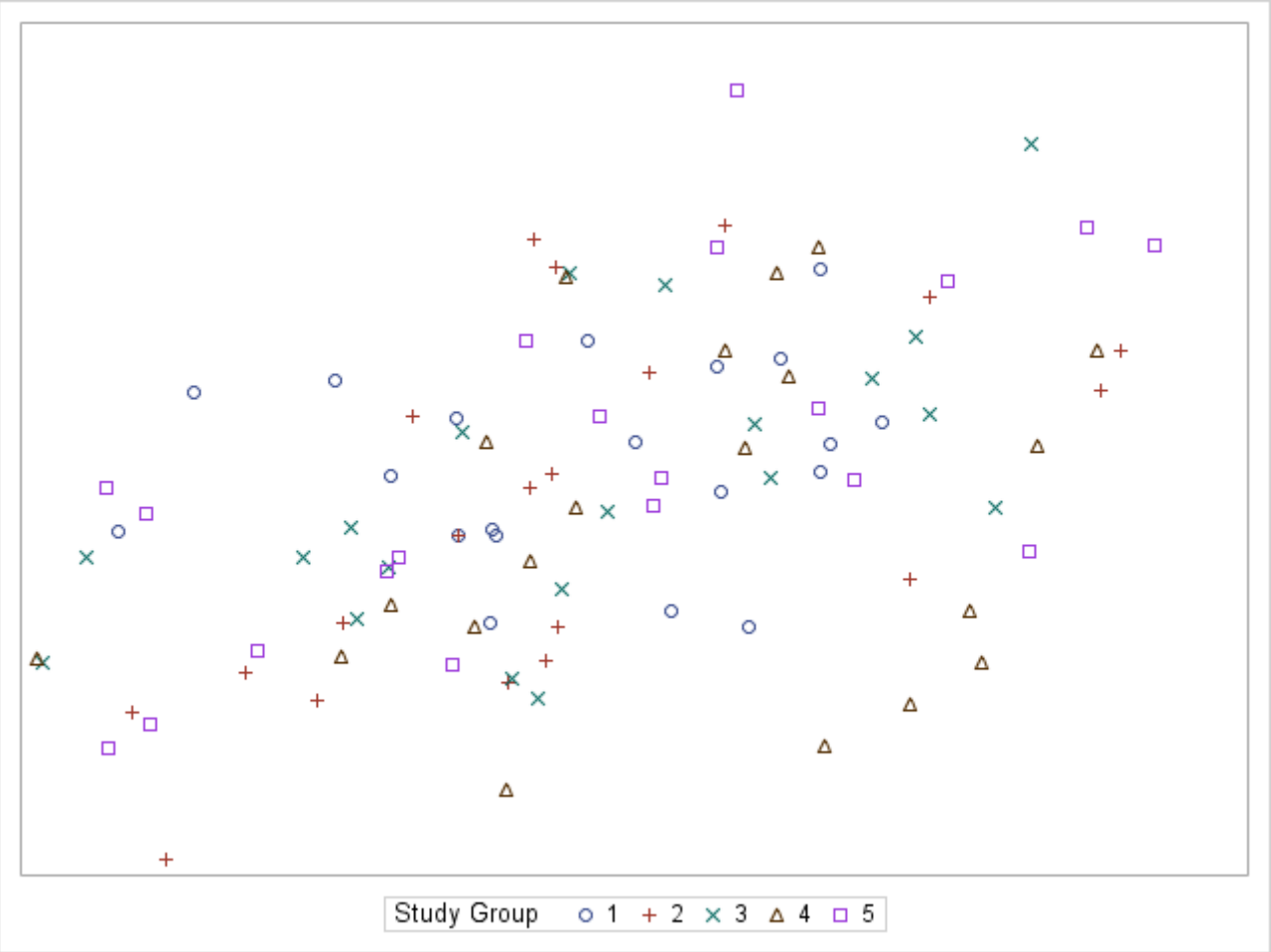
Figure 15: Geometric Mean Titers of Neutralizing Antibody against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 16: Geometric Mean Titers of Hemagglutination Inhibition Antibody against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 17: Geometric Mean Titers of Neutralizing Antibody against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 18: Correlation of Hemagglutination Inhibition Antibody and Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Modified Intent-to-Treat Population

[Implementation Note: A generic sample figure is shown below. The scatter plots should be presented in a single figure with separate panels for each visit (Day 1, Day 8, Day 22, D181). Visit labels should be included in the panel header. Within each panel distinct marker types and colors should be used to indicate the treatment arms, with treatment group labels included in a legend. Each treatment arm should have a separate color, with marker shape used to distinguish strata. The spearman correlation should be calculated over all subjects and annotated within each panel as "Spearman Correlation (r=0.xx, p=0.xx)"]



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Figures with similar format:

Figure 19: Correlation of Hemagglutination Inhibition Antibody and Neutralizing Antibody Against A/Hong Kong/125/2017 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 20: Correlation of Hemagglutination Inhibition Antibody and Neutralizing Antibody Against A/Shanghai/2/2013 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 21: Correlation of Hemagglutination Inhibition Antibody and Neutralizing Antibody Against A/Guangdong/17F003/2016 (H7N9) by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 22: Correlation of A/Hong Kong/125/2017 (H7N9) and A/Shanghai/2/2013 (H7N9) Hemagglutination Inhibition Antibody Results by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 23: Correlation of A/Hong Kong/125/2017 (H7N9) and A/Shanghai/2/2013 (H7N9) Neutralizing Antibody Results by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 24: Correlation of A/Hong Kong/125/2017 (H7N9) and A/Guangdong/17F003/2016 (H7N9) Hemagglutination Inhibition Antibody Results by Study Day, Stratum and Study Group, Per-Protocol Population

Figure 25: Correlation of A/Hong Kong/125/2017 (H7N9) and A/Guangdong/17F003/2016 (H7N9) Neutralizing Antibody Results by Study Day, Stratum and Study Group, Per-Protocol Population

14.3.1.1 Solicited Adverse Events

Figure 26: Maximum Severity of Solicited Systemic Symptoms per Subject by Day Post Vaccination, Stratum and Study Group, Safety Population

[Implementation Note: A Generic figure is shown below. A horizontal bar chart should be presented in 3 image files (each study group and overall) with separate panels for each stratum (6 panels (each stratum and all subjects) split into 3 columns and 2 rows). Axes should be labeled as follows: x-axis label: Study Day, y-axis label: Percentage of Subjects (%). The study groups should be indicated in the panel headers including "(N=X)", where N = the number of subjects in the Safety Population who received the relevant dose. Subjects are counted at most once at the maximum severity across all systemic events reported for the specified time point]

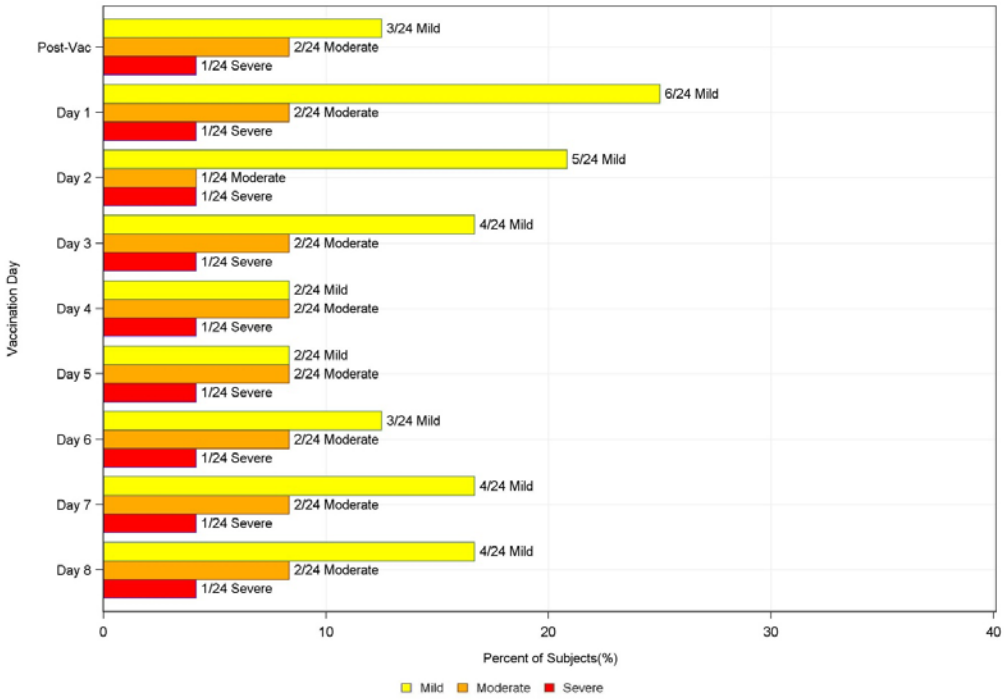


Figure with similar format:

Figure 27: Maximum Severity of Solicited Injection Site Symptoms per Subject by Day Post Vaccination, Stratum and Study Group, Safety Population

14.3.1.2 Unsolicited Adverse Events

Figure 28: Frequency of Related Adverse Events by MedDRA System Organ Class, Severity, Stratum and Study Group, Safety Population

[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all vaccinations. A horizontal bar chart should be presented in 3 image files (each study group and overall) with separate panels for each stratum (6 panels (each stratum and all subjects) split into 3 columns and 2 rows). Axes should be labeled as follows: y-axis label: System Organ Class, y-axis label: Number of Events. The strata should be indicated in the panel headers including "(N=X)", where N = the number of subjects 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]

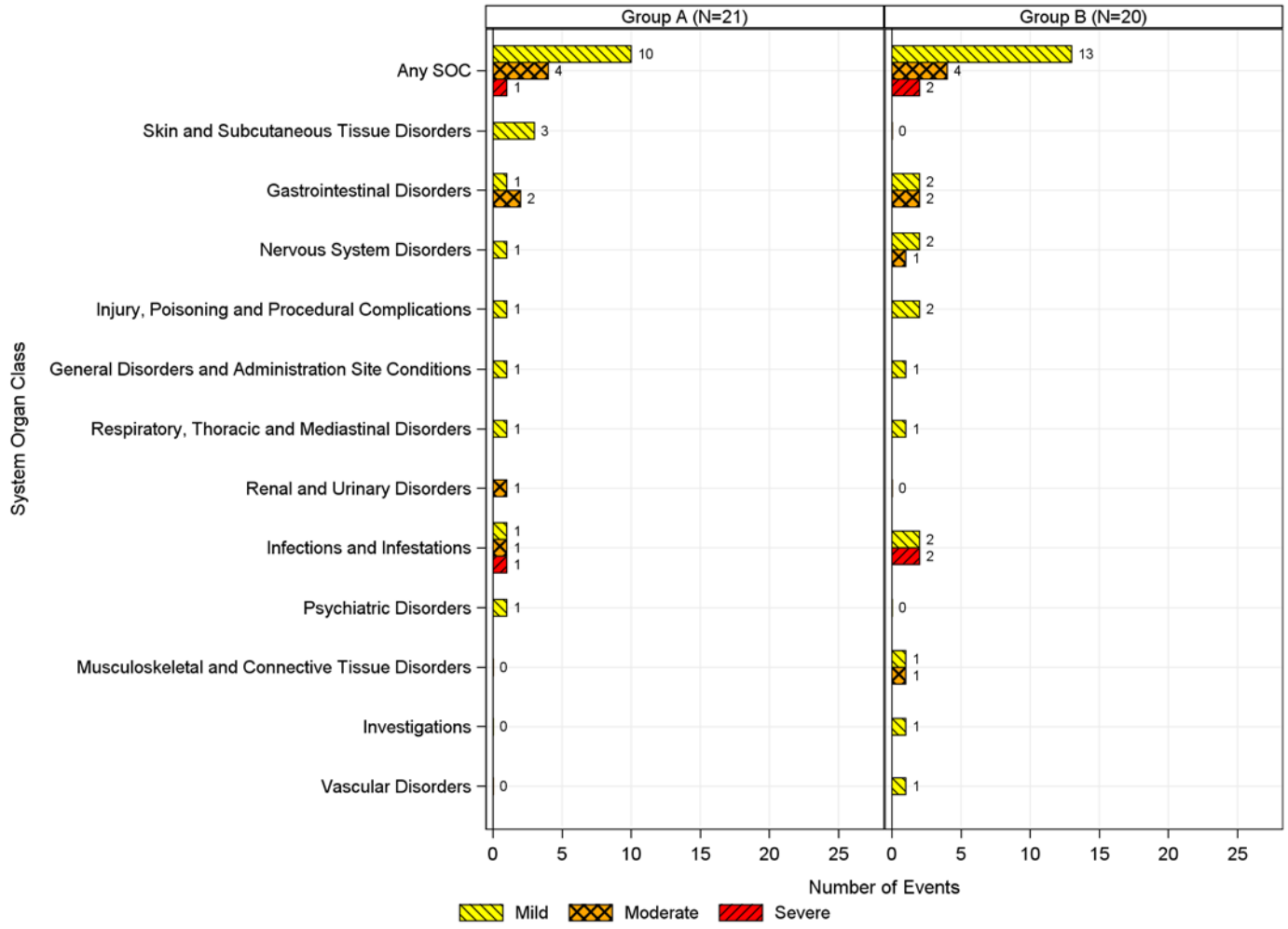


Figure 29: Incidence of Related Adverse Events by MedDRA® System Organ Class, Maximum Severity, Stratum and Study Group, Safety Population

[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all vaccinations. A horizontal bar chart should be presented in 3 image files (each study group and overall) with separate panels for each stratum (6 panels (each stratum and all subjects) split into 3 columns and 2 rows). Axes should be labeled as follows: y-axis label: System Organ Class, x-axis label: Percentage of Subjects (%). The strata should be indicated in the panel headers including "(N=X)", where N = the number of subjects 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]

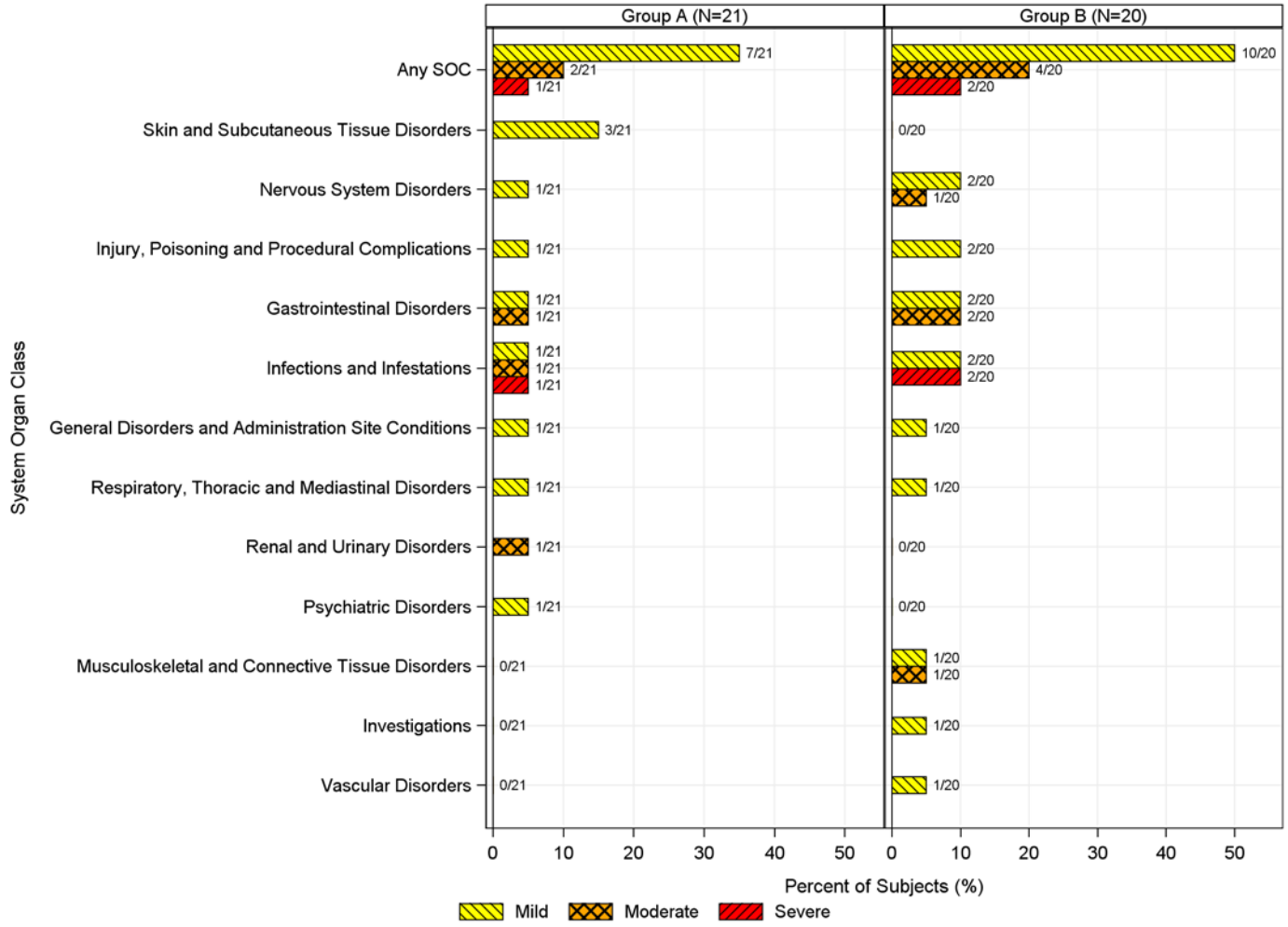


Figure 30: Frequency of Adverse Events by MedDRA System Organ Class, Relationship to Vaccination, Stratum and Study Group, Safety Population

[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all vaccinations. A horizontal bar chart should be presented in 3 image files (each study group and overall) with separate panels for each stratum (6 panels (each stratum and all subjects) split into 3 columns and 2 rows). Axes should be labeled as follows: y-axis label: System Organ Class, y-axis label: Number of Events. The strata should be indicated in the panel headers including "(N=X)", where N = the number of subjects 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]

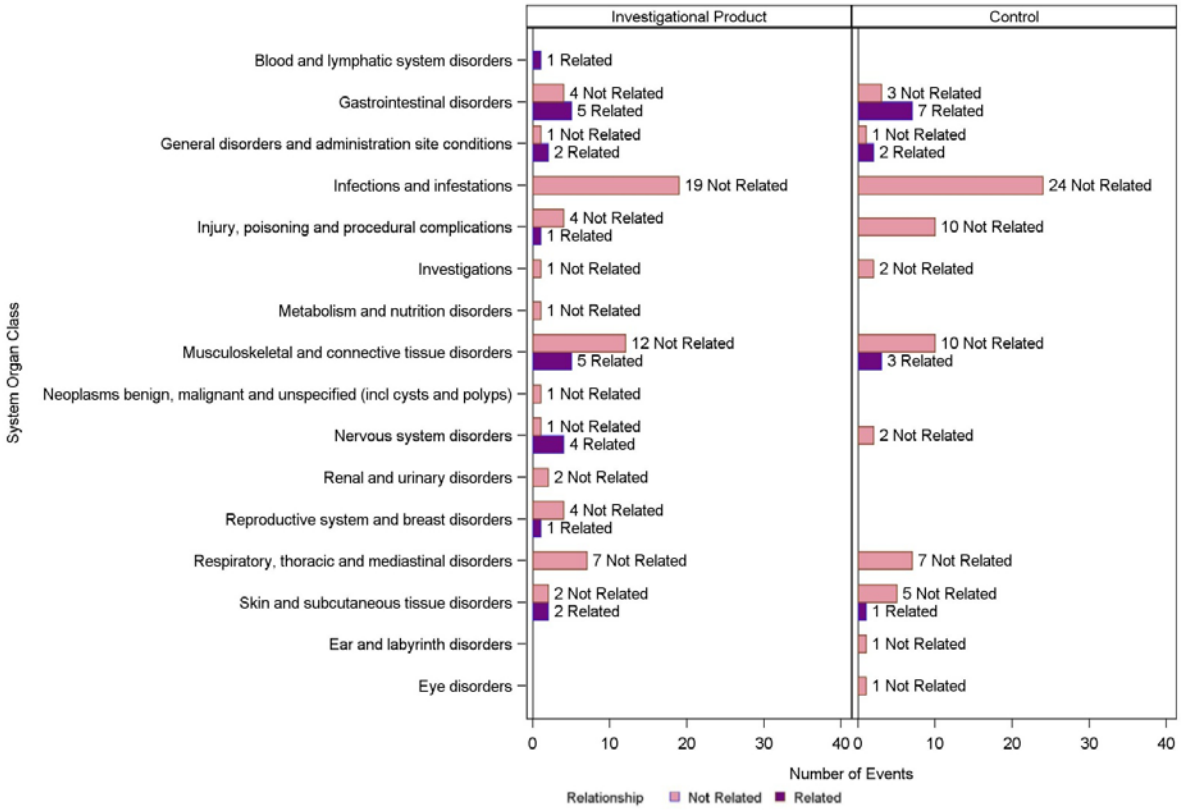
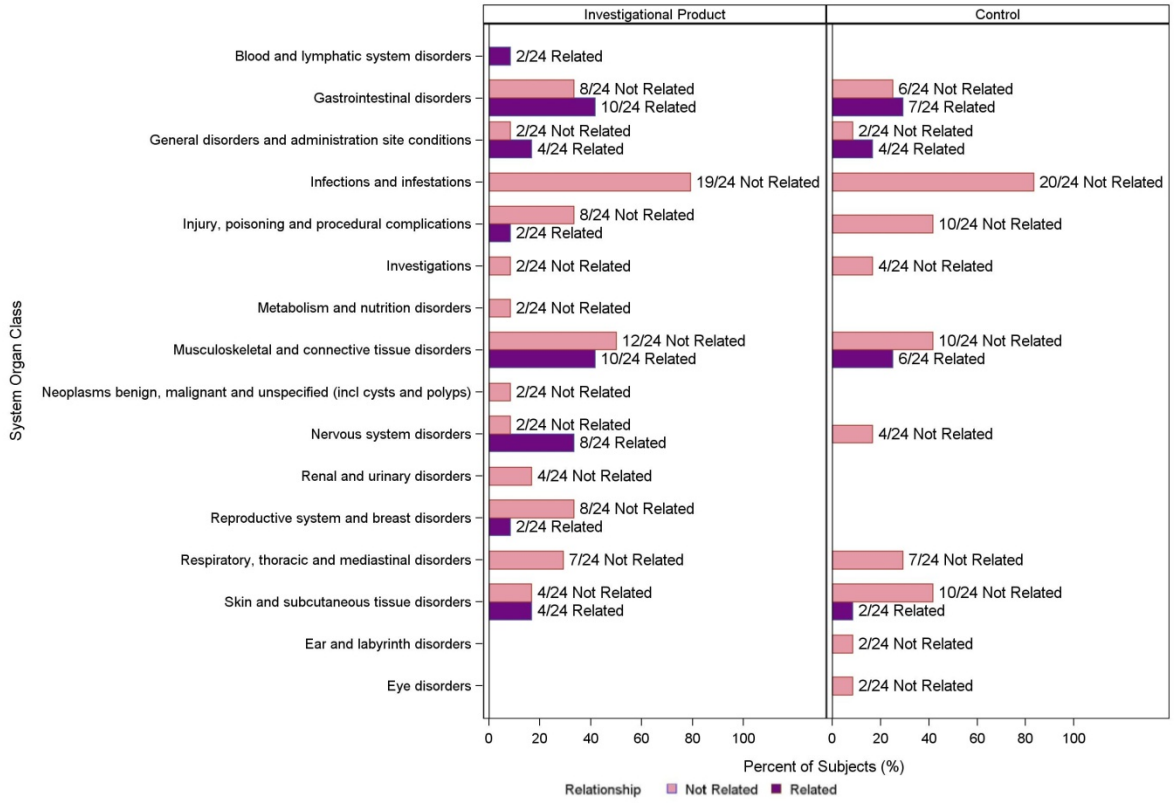


Figure 31: Incidence of Adverse Events by MedDRA System Organ Class, Relationship to Vaccination, Stratum and Study Group, Safety Population

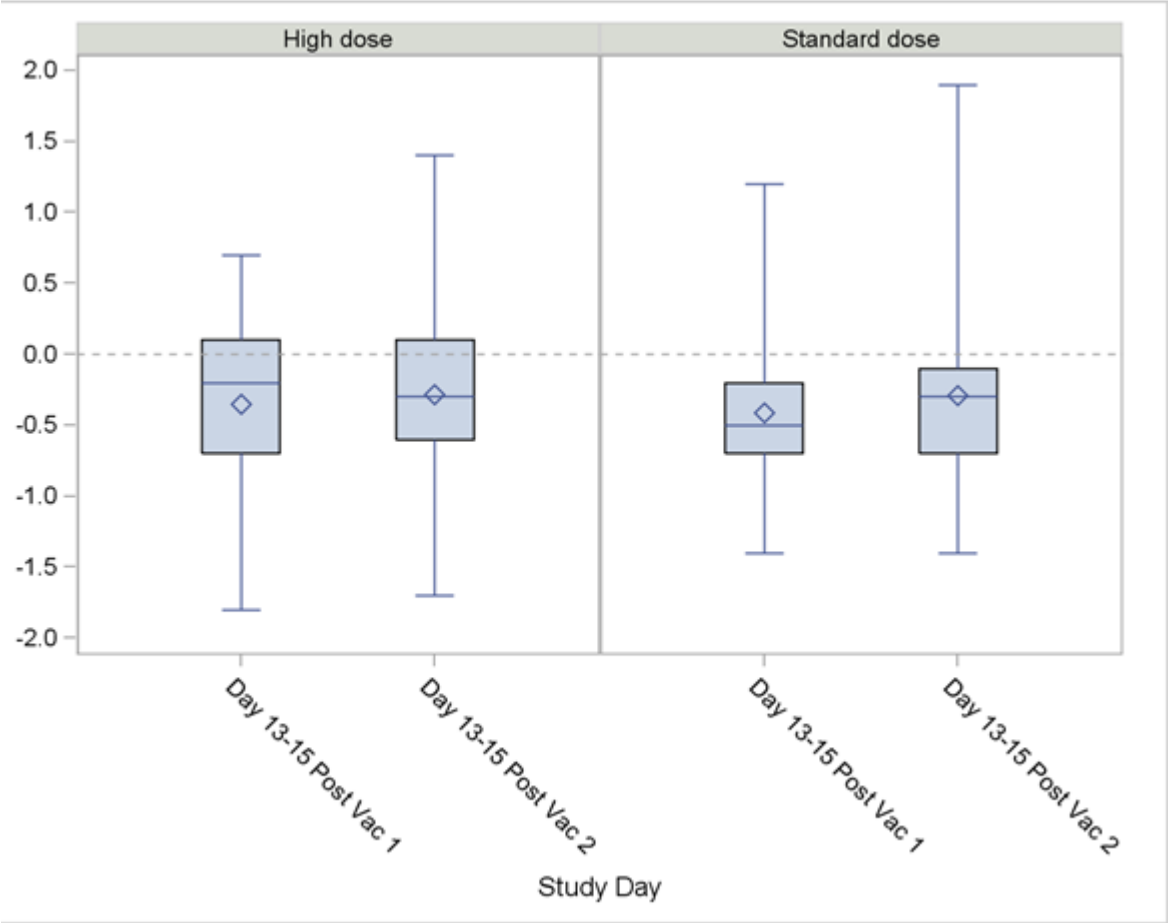
[Implementation Note: A Generic figure is shown below. This figure includes all unsolicited events across all vaccinations. A horizontal bar chart should be presented in 3 image files (each study group and overall) with separate panels for each stratum (6 panels (each stratum and all subjects) split into 3 columns and 2 rows). Axes should be labeled as follows: y-axis label: System Organ Class, x-axis label: Percentage of Subjects (%). The strata should be indicated in the panel headers including "(N=X)", where N = the number of subjects 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]



14.3.5.1 Displays of Laboratory Results - Chemistry

Figure 32: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – Alanine Aminotransferase, Safety Population

[Implementation note: A generic figure is shown below. Plot should be generated with all study groups in a single image file with panels for each study group and strata (5 rows (strata) x 2 columns (study groups)) with a box plot shown for each post-baseline study day that labs are drawn (D8). Y-axis should be labeled "[Parameter] Change from baseline ([units]). Repeat for all clinical laboratory parameters: WBC, Hgb, PLT, ALT, T. Bili, Cr]



Figures with similar format:

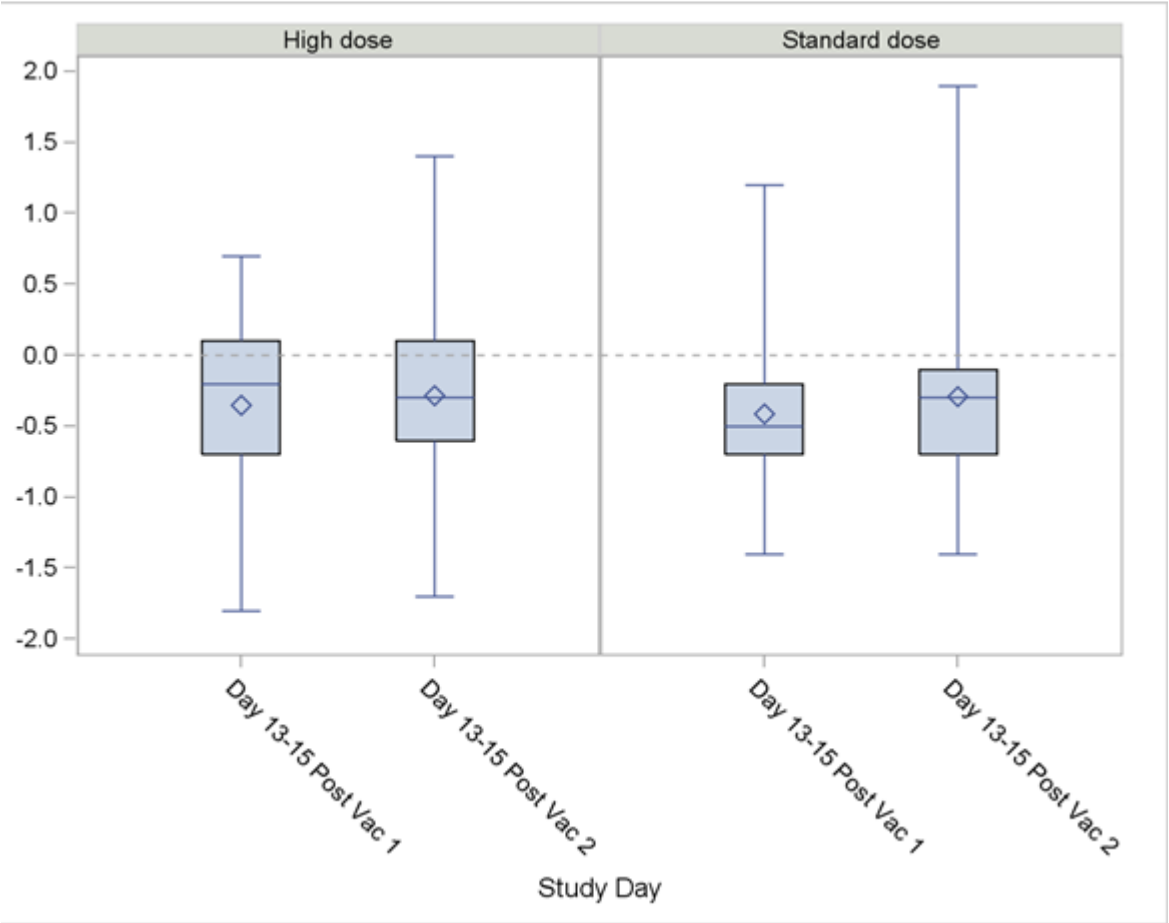
Figure 33: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – Total Bilirubin, Safety Population

Figure 34: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – Creatinine, Safety Population

14.3.5.2 Displays of Laboratory Results - Hematology

Figure 35: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – Hemoglobin, Safety Population

[Implementation note: A generic figure is shown below. Plot should be generated with all study groups in a single image file with panels for each study group and strata (5 rows (strata) x 2 columns (study groups)) with a box plot shown for each post-baseline study day that labs are drawn (D8). Y-axis should be labeled "[Parameter] Change from baseline ([units]). Repeat for all clinical laboratory parameters: WBC, Hgb, PLT, ALT, T. Bili, Cr]



Figures with similar format:

Figure 36: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – White Blood Cells, Safety Population

Figure 37: Laboratory Results by Scheduled Visits: Mean Changes from Baseline by Laboratory Parameter, Stratum and Study Group – Platelets, Safety Population

APPENDIX 3. LISTINGS MOCK-UPS

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LISTINGS

16.1.6 Listing of Subjects Receiving Investigational Product

Listing 1 16.1.6 - Listing of Subjects Receiving Investigational Product

Subject ID	Randomized Study Group	Stratum	Product Received Study Vaccination 1

16.2 Database Listings by Subject

16.2.1 Discontinued Subjects

Listing 2 16.2.1 - Early Terminated Subjects

[Implementation Note: In the "Reason" column, concatenate any "specify" fields, including AE number and DV number.]

Study Group	Stratum	Subject ID	Reason for Early Termination	Study Day

16.2.2 Protocol Deviations

Listing 3 16.2.2.1 - Subject-Specific Protocol Deviations

[Implementation Note: In the "Deviation" column, concatenate any and all "specify" fields (including visit number, etc.). If "Reason for Deviation" is "Other," concatenate "specify" field, separate by a colon, e.g., "Other: Subject refusal."]

Study Group	Stratum	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

[Implementation Note: In the "Deviation" column, concatenate any and all "specify" fields (including visit number, etc.). If "Reason for Deviation" is "Other," concatenate "specify" field, separate by a colon, e.g., "Other: Subject refusal."]

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 Efficacy Analysis

Listing 5 16.2.3 - Subjects Excluded from Analysis Populations

[Implementation Note: This data in this listing should be congruent with the "Analysis Populations by Study Group" table. The reasons included here should match the SAP text that describes who will be excluded from analyses.]

Study Group	Stratum	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.						

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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)."]

Study Group	Stratum	Subject ID	Sex	Age at Enrollment (years)	Ethnicity	Race	BMI	Seasonal Influenza Received (2017-2018)	Seasonal Influenza Received (2018-2019)

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

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

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

Listing 8 16.2.5: Compliance and/or Drug Concentration Data

Not applicable for this study.

16.2.6 Individual Efficacy/Immunogenicity Response Data

Listing 9 16.2.6.1 - Individual Efficacy/Immunogenicity Response Data – Hemagglutination Inhibition Antibody Results

Study Group	Stratum	Subject ID	Planned Study Day	Actual Study Day	Strain	Titer Replicate 1	Titer Replicate 2

Listing with similar format:

Listing 10 16.2.6.2 - Individual Efficacy/Immunogenicity Response Data – Neutralizing Antibody Results

16.2.7 Adverse Events

Listing 11 16.2.7.1 - Solicited Events – Systemic Symptoms

Study Group	Stratum	Subject ID	Post Vac Day	Assessment[a]	Symptom	Severity	Attributed to Alternate Etiology?[b]	Alternate Etiology
				MA				
				Clinic				

Note: [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.)

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Listing 12 16.2.7.2: Solicited Events – Injection Site Symptoms

Study Group	Stratum	Subject ID	Post Vac 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.

[b] Grade 3 events only.

Note: Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)

Listing 13 16.2.7.3: Unsolicited Adverse Events

Adverse Event	No. of Days Post Vac (Duration)	Severity	SAE?	Relationship to Study Treatment	In Not Related, Alternative Etiology	Subject Terminated Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Treatment Group: , Subject ID: , AE Number:									
Comments:									
Treatment Group: , Subject ID: , AE Number:									
Comments:									
Note: For additional details about SAEs, see Table: xx.									

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16.2.8 Individual Laboratory Measurements

Listing 14 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.]

Study Group	Stratum	Subject ID	Planned Study Day	Actual Study Day	Sex	Age (years)	Laboratory Parameter (Units)	Result (Severity)	Reference Range Low	Reference Range High

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Listing 15 16.2.8.2: Clinical Laboratory Results – Hematology

Study Group	Stratum	Subject ID	Planned Study Day	Actual Study Day	Sex	Age (years)	Laboratory Parameter (Units)	Result (Severity)	Reference Range Low	Reference Range High

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16.2.9 Vital Signs and Physical Exam Findings

Listing 16 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).]

Study Group	Stratum	Subject ID	Planned Study Day	Actual Study Day	Temperature (°C)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Heart Rate (beats/min)	Weight (kg)	Height (cm)

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Listing 17 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 Description and Number in parentheses, e.g., "Yes (AE; 001)".]

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

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16.2.10 Concomitant Medications

Listing 18 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 Description and Number in parentheses, e.g., "Yes (AE; 001)".]

Study Group	Stratum	Subject ID	CM Number	Medication	Medication Start Day	Medication End Day	Indication	Taken for an AE? (AE Description; Number)	Taken for a condition on Medical History? (MH Description; 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 19 16.2.11.1: Pregnancy Reports – Maternal Information

Study Group	Stratum	Subject ID	Pregnancy Number	Study Day Corresponding to Estimated Date of Conception	Source of Maternal Information	Pregnancy Status	Mother's Pre-Pregnancy BMI	Mother's Weight Gain During Pregnancy (LB)	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 20 16.2.11.2: Pregnancy Reports – Gravida and Para

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

Listing 21 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 (weeks)	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 22 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 (weeks)	Size for Gestational Age	Cord pH	Congenital Anomalies?	Autopsy Performed?	If Autopsy, Etiology for Still Birth Identified?

Listing 23 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 (weeks)	Abnormality in Product of Conception?	Reason for Therapeutic Abortion