

Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in
Participants Aged 18 to 60 Years

QUADRIFLU

Case Record Form

Visit 1 Screening

Site-Participant number: □-□□□
Date of visit (DD/MMM/YYYY): □□/□□□□/□□□□
Date of informed consent signed (DD/MMM/YYYY): □□/□□□□/□□□□

Demographic

Date of Birth (DD/MMM/YYYY): □□/□□□□/□□□□ Age: □□ years

Physical Examination

Body Temperature: □□ °C

Medical History

Pregnancy

Pregnancy status: not pregnant N/A (male participant)
 currently pregnant currently lactating
 plan to become pregnant during study period

Vaccine

Vaccination history: received any vaccine within 4 weeks
 received any vaccine for more than 4 weeks
 never received any vaccine
Vaccination plan: plan to received vaccination in 3 weeks
 plan to received vaccination more than 3 weeks
 not planned to received any vaccine

Influenza

Influenza vaccination history: received influenza vaccine in the past 6 months
 received influenza vaccine for more than 6 months
 never received influenza vaccine
Influenza illness history: had influenza illness in the past 6 months
 had influenza illness more than 6 months
 never had influenza illness

Chronic illness

Currently have chronic illness No
 Yes (please specify) _____

Interviewed by _____

Laboratory

Collection time (24 hrs.): □□:□□ Received time (24 hrs.): □□:□□
Collected by _____ Received specimen by _____
Pregnancy test: Positive Negative
 N/A (male participant)
Performed by _____ Approved by _____ Report time (24 hrs.): □□:□□

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Visit 2 Enrollment

Site-Participant number: -
Date of visit (DD/MMM/YYYY): /

Demographic

Date of Birth (DD/MMM/YYYY): / Age: years
Sex Male Female
Race Asian White Other (please specify) _____

Physical Examination

Body Temperature: °C Height cm. Weight kg.

Cardiovascular

Systolic BP mmHg Diastolic BP mmHg Pulse rate bpm
Other cardiovascular finding N/A
 Remark (please specify) _____

Chest

Respiratory rate breaths per bpm
Other chest finding N/A
 Remark (please specify) _____

HEENT

Head Normal Abnormal (please specify) _____
Eyes Normal Abnormal (please specify) _____
Ears Normal Abnormal (please specify) _____
Nose Normal Abnormal (please specify) _____
Throat/Mouth Normal Abnormal (please specify) _____

Abdomen

Other abdominal finding N/A
 Remark (please specify) _____

Musculoskeletal

Other musculoskeletal finding N/A
 Remark (please specify) _____

Neurological

Other Neurological finding N/A
 Remark (please specify) _____

Other body systems

Other finding N/A
 Remark (please specify) _____

Conclusion

Eligible to take part in the study Yes
 No (please specify) _____

Performed physical examination by _____ Approved to enroll in the study by _____

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Visit 2 Enrollment

Site-Participant number: -

Laboratory

Date of sample collection (DD/MMM/YYYY): //

Collection time (24 hrs.): :

Collected by _____

Received specimen by _____

Laboratory results

A/H1N1 Antibody

Titer: 1:

A/H3N2 Antibody

Titer: 1:

B/Yamagata Antibody

Titer: 1:

Performed by _____

Approved by _____

Report time (24 hrs.): :

Vaccination

Date of vaccination (DD/MMM/YYYY): //

Vaccine lot:

Expiration date (DD/MMM/YYYY): //

Preparation Time (24 hrs.): :

Injection Time (24 hrs.): :

Vaccination Arm:

Quadrivalent inactivated Influenza vaccine (QIV)

Trivalent inactivated Influenza vaccine (TIV)

Injected by _____

Vaccine Prepared by _____

Solicited Reaction

Type of solicited reaction

Pain

Redness

Swelling Induration

Ecchymosis

Fever

Headache

Malaise

Shivering

Observed by _____