Mahidol University
Faculty of Tropical Medicine

TMHG 550

LIFE
Learning to Investigate by Field Experiment

Case Report Form

QUADRIFLU

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

Based on protocol: Version 1.0 dated 18 Feb 2020

Site Number: |__|	Patient Screen ID: |__||__||__|

Protocol No. QUADRIFLU	Site No ☐	Patient Screen ID ☐☐☐	**Screening visit V1**

Screening Visit (V1)

Date of visit: |__|__|-|__|__|__|- 20 |__|__| (*DD–MMM–YYYY*)

Inclusion Criteria Patient must meet all of the following criteria to be eligible for enrolment into the study		**Yes**	**No**
1.	Aged 18 to 60 years on the day of inclusion?	☐	☐
2.	Able to provide written informed consent prior to any study procedure?	☐	☐
3.	For female participants, must have negative urine pregnancy test at enrollment and willing to take reliable birth control measures for 1 month after vaccination?	☐	☐
4.	Able to attend all scheduled visits and to comply with all trial procedures?	☐	☐

Exclusion Criteria Patient meeting any of the following criteria is not eligible for enrolment into the study:		**Yes**	**No**
1.	Pregnant, lactating women or female who intends to become pregnant during the study period?	☐	☐
2.	Receipt of any vaccine during the 4 weeks preceding the trial vaccination or planned receipt of any vaccine during the 3 weeks following the trial vaccination?		
3.	Vaccination against influenza (in a clinical trial or a flu vaccination campaign) or self-reported history of influenza infection (having influenza-like illness) in the past 6 months?	☐	☐
4.	Febrile illness (body temperature ≥ 38.0□C) on the day of vaccination (temporary exclusion, a prospective participant should not be included in the study until the febrile event has subsided)?	☐	☐
5.	Chronic illness that, in the opinion of the investigator, is at a stage where it might interfere with trial conduct or completion or would increase the risk to the individual by participating in this study?	☐	☐

Urine Pregnancy Test (For females only)			
Test Date	|__|__|-|__|__|__|-|__|__|__|__| (*dd–MMM–yyyy*)	**Test Result**	☐ Negative ☐ Positive

Protocol No. QUADRIFLU	Site No ☐	Patient Random ID ☐☐☐	**Enrollment visit** **V2**

Enrollment Visit (V2)

Date of visit: |__|__|-|__|__|__|- 20 |__|__| (*dd–MMM–y)*

Informed Consent Form

Date of signing informed consent: |__|__|-|__|__|__|- 20 |__|__| **Time:** |__|__|.|__|__|
(*dd–MMM–yyyy)* (*HH:MM)*

Patient's Demographics

Year of birth:|__|__|__|__| (*YYYY)*

Gender: □ Male □ Female

If Female, is the patient pregnant? □No □Yes → Excluded

Race/Ethnicity: □ White □ Black □ Caucasian □ Asian □ Other……

Marital Status: □ Single □ Married □ Divorced □ Widow

Education: □ None □ Basic/ Primary □ Secondary □ College Graduate/ Higher

Employment: □ Employed □ Unemployed □ Retired

Residence: □ Rural □ Urban

Patient's Vital signs

Weight: |__||__||__|.|__|kg **Height:** |__||__||__|cm **Temperature:** |__||__|.|__|°C

Systolic blood pressure*:|__||__||__|mmHg **Diastolic blood pressure*:**|__||__||__|mmHg

** to be measured in dominant arm, after 5 minutes of rest in a sitting position*

Heart rate: |__||__||__|beats/min. **Respiration Rate :** |__||__| breaths/min

Protocol No. QUADRIFLU	Site No ☐	Patient Random ID ☐☐☐	**Enrollment visit V2**

Physical Examination

Examination	Date (*dd–MMM–yyyy*)	Result	Specify/Comment
Head	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Eyes	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Ears	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Nose	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Throat	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Cardiovascular	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Chest	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Abdomen	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Musculoskeletal	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Neurological	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Other ……..	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Other ……..	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……
Other ……..	|__|__|-|__|__|__|- 20 |__|__|	☐ Normal ☐ Abnormal	……..…….……

Physical Examination Outcome: ☐ Normal ☐ Abnormal

If abnormal, in your the opinion, is at a stage where it might interfere with trial conduct or completion or would increase the risk to the individual by participating in this study? Please review exclusion criteria number 5".

Eligibility Check

According to the Inclusion and Exclusion Criteria, Is the patient eligible to participate in the study?

☐ Yes ☐ No

If No, please specify the reason.....

Protocol No. QUADRIFLU	Site No ☐	Patient Random ID ☐☐☐	**Enrollment visit** **V2**

Laboratory tests results		
Test Name	**Date & Time of Sample Collection** (*dd–MMM–yyyy) (HH:MM)*	**Result**
A/H1N1 Antibody Titer	|__|__|-|_ |__|__|- 20 |__|__|, |_|_|:|_|_|	……..
A/H3N2 Antibody Tite	|__|__|-|_ |__|__|- 20 |__|__|, |_|_|:|_|_|	……..
B/Yamagata-lineage Antibody Titer	|__|__|-|_ |__|__|- 20 |__|__|, |_|_|:|_|_|	……..
B/Victoria-lineage Antibody Titer	|__|__|-|_ |__|__|- 20 |__|__|, |_|_|:|_|_|	……..

Vaccine Administration

Date of visit: \|__\|__\|-\|__\|__\|__\|- 20 \|__\|\|__\| (*DD–MMM–YYYY)* **Time:** \|__\|__\|:\|__\|\|__\| (*HH:MM)*

Vaccination Arm

☐ Group 1 - Quadrivalent influenza vaccine (QIV)

☐ Group 2 - Trivalent influenza vaccine (TIV) (control group)