QUADRIFLU Case Report Form
Screening and Enrollment

Instruction to investigator

1. Please tick the checkbox for the answer or write down the answer in the given area.
2. For the question with multiple answers, mark the checkboxes as necessary.
3. If the subject gives the answers not listed, select other and and specify the anwer.

Screening

Date _____/_____/_____
DD MMM YYYY

Study Site ☐ Hospital A Bangkok: ☐ Hospital B Chiang Mai

Subject ID |___|___|___|___|	Investigator ID |___|___|___|___|

Inclusion Criteria

Subjects who meets the inclusion critieria will be checked in 'Yes'. Otherwise check in 'No' (✓ Yes or No)

Criteria	Yes	No
1. Age: 18 to 60 years		
2. Able to provide written informed consent		
3. Female participant who has not plan to be preganant within 1 month after vaccination		
4. Able to attend all scheduled visits and comply all trial procedures		

Exclusion Criteria

Subjects who meets the exclusion critieria will be checked in 'Yes'. Or else 'No' (✓ for Yes or No)

Criteria	Yes	No
1. Pregnant or lactating or female who intends to become pregnant during study period		
2. Receive any vaccine within 4 weeks preceding the trial vaccination		
3. Planned receipt of any vaccine during the 3 weeks following the trial vaccination		
4. Received influenza vaccine in the past 6 months		
5. Had influenza illness in the past 6 months		
6. Body temperature > 38°C on the day of vaccination (temporary exclusion)		
7. Chronic illness at a stage that might interfere with trial conduct or completion or would increase the risk to the individual		
8. Pregnancy test (laboratory)		

Instruction

1. Subject who meets the inclusion criteria will be enrolled in the project.
2. Subject who meets the exclusion criteria will be rejected.

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Enrollment

Demographic

Age |___|___| in years	Nationality ☐ Thai : ☐ Non-Thai Asian ☐ Other
Gender ☐ Male : ☐ Female : ☐ Other	Ethnic _____
Regular smoking ☐ Yes : ☐ No	Weight |___|___| in kg
Regular drinking ☐ Yes : ☐ No	Height |___|___| in cm

Medical History

Chronic Diseases	Well controlled	Not
☐ Heart disease	☐	☐
☐ Diabetes	☐	☐
☐ Hypertension	☐	☐
☐ Kidney disease	☐	☐
☐ Liver disease	☐	☐
☐ Seizure	☐	☐
☐ Endocrine disease	☐	☐
☐ Cancer	☐	☐
☐ HIV	☐	☐
☐ Other, Specify _____	☐	☐
_____		
_____		

Regular taking drug

_____

_____

_____

Vaccination history (within 6 months) ☐ Yes : ☐ No (If yes, please answer below. Or skip below)

Type of vaccine	When
☐ Influenza	_____
☐ Covid-19	_____
☐ Hepatitis B	_____
☐ Chickepox	_____
☐ Pneumococcal	_____
☐ Meningococcal	_____
☐ Other, Specify _____	_____
_____	

Allergic history ☐ Yes : ☐ No

If yes, please specify to specific drug and reaction _____

_____

Physical Examination	
Height |___|___| in cm	Pulse Rate |___|___|___| beats per minute
Weight |___|___| in kg	Respiratory Rate |___|___| times per minute
Temparature |___|___| ° Celsius	Blood pressure ____/____ mmHg

Vaccine

Batch/Lot number |___|___|___|___|___|___|

Site of administration

☐ Arm

☐ Thigh

☐ Buttock

Date and Time of administration

Date _____/_____/_____

DD MMM YYYY

Time ____:____ in 24hr format

H H M M

Laboratory

Haeagglution Inhibition Assay

☐ < 40 titres

☐ ≥ 40 titres

Immediate adverse event (within 30 minutes) ☐ Yes : ☐ No

(If yes, please answer below. Or skip below)

Local reactions	Systemic reactions
☐ Pain	☐ Fever (> 38 ° Celsius)
☐ Redness	☐ Headache
☐ Swelling	☐ Malaise
☐ Induration	☐ Myalgia
☐ Ecchymosis	☐ Shivering
	☐ Shock

Hospitalization immediately after vaccination ☐ Yes : ☐ No