

Case Report Form (Protocol name: QUADRIFLU)

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

Screening Visit Form	Study ID	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
		Site ID	-	Participant ID			

Date of visit (DD/MM/YYYY)

 / /

Date of informed consent signed (DD/MM/YYYY)

 / /

Eligibility Criteria	
1. Age	<input type="text"/> <input type="text"/> Years
2. Sex	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown <input type="radio"/> Undifferentiate
3. Body temperature	<input type="text"/> <input type="text"/> . <input type="text"/> °C
4. Are you pregnant?	<input type="radio"/> Yes <input type="radio"/> No
5. Are you in lactation period?	<input type="radio"/> Yes <input type="radio"/> No
6. Did you received any vaccine within 4 weeks?	<input type="radio"/> Yes <input type="radio"/> No
7. Do you plan to receive vaccine during 3 weeks?	<input type="radio"/> Yes <input type="radio"/> No
8. Did you received influenza vaccine in the past 6 months?	<input type="radio"/> Yes <input type="radio"/> No
9. Did you have influenza illness in the past 6 months?	<input type="radio"/> Yes <input type="radio"/> No
10. Do you have any chronic illness?	<input type="radio"/> Yes <input type="radio"/> No

Laboratory	
1. Pregnancy test result	<input type="radio"/> Positive <input type="radio"/> Negative

Case Report Form (Protocol name: QUADRIFLU)

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

Enrollment Form	Study ID	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		Site ID - Participant ID	of visit	(D D / M M / Y Y Y Y)

1. Demographics	
1.1 Year of birth <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	1.2 Age <input type="text"/> <input type="text"/> years
1.3 Sex <input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknow <input type="radio"/> Undifferentiate	1.4 Race <input type="radio"/> Thai <input type="radio"/> Other (Please specify) _____

2. Physical Examination	
2.1 Weight <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> kg.	2.2 High <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm.
2.3 Blood pressure <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg <i>systolic diastolic</i>	2.4 Pulse rate <input type="text"/> <input type="text"/> <input type="text"/> bpm
2.5 Respiraory rate <input type="text"/> <input type="text"/> <input type="text"/> bpm	2.6 Body temperature <input type="text"/> <input type="text"/> . <input type="text"/> °C
2.7 HEENT (head, eyes, ears, nose, and throat)	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
2.8 Cardiovascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
2.9 Chest	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
2.10 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
2.11 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
2.12 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____
body systems	<input type="radio"/> Normal <input type="radio"/> Abnormal (Please specify) _____

Case Report Form (Protocol name: QUADRIFLU)

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

Enrollment Form	Study ID	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
		Site ID - Participant ID	of visit	(D D / M M / Y Y Y Y)

Eligibility check	<input type="radio"/> Yes	<input type="radio"/> No
--------------------------	---------------------------	--------------------------

3.Vaccination	
3.1 Date of vaccination <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (D D / M M / Y Y Y Y)	3.2 Time of vaccination <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hour : minute)
3.3 Type of vaccine <input type="radio"/> 1: QIV <input type="radio"/> 2: TIV	3.4 Vaccination arm <input type="radio"/> Right arm <input type="radio"/> Left arm

4.Laboratory	
4.1 Date of Sample collection <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (D D / M M / Y Y Y Y)	4.2 Time of sample collection <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hour : minute)
Antibody	Titer
4.3 A/H1N1	<input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/>
4.4 A/H3N2	<input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/>
4.5 B/Yamagata	<input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/>

5.Solicited Reaction		
5.1 Pain	<input type="radio"/> Yes	<input type="radio"/> No
5.2 Readness	<input type="radio"/> Yes	<input type="radio"/> No
5.3 Swelling	<input type="radio"/> Yes	<input type="radio"/> No
5.4 Induration	<input type="radio"/> Yes	<input type="radio"/> No
5.5 Ecchymosis	<input type="radio"/> Yes	<input type="radio"/> No
5.6 Fever	<input type="radio"/> Yes	<input type="radio"/> No
5.7 Headache	<input type="radio"/> Yes	<input type="radio"/> No
5.8 Malaise	<input type="radio"/> Yes	<input type="radio"/> No
5.9 Shivering	<input type="radio"/> Yes	<input type="radio"/> No
5.10 Not found any solicited reaction	<input type="radio"/> Yes	<input type="radio"/> No