

Study Code:	Subject ID:	<input type="text"/> <input type="text"/> <input type="text"/>	Subject initials:	<input type="text"/> <input type="text"/> <input type="text"/>
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**CASE REPORT FORM**  
**Version 1.0 (12-May-2022)**  
**Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in**  
**Participants Aged 18 to 60 Years**  
**QUADRIFLU**

CLINICAL TRIAL SITE/UNIT:	<b>HOSPITAL BANGKOK (A) <sup>1</sup></b>	<input type="text"/>
	<b>HOSPITAL CHIANG MAI (B) <sup>2</sup></b>	<input type="text"/>
PRINCIPAL INVESTIGATOR:	<b>Dr. PI. Principal</b>	

Subject Initials:	<input type="text"/> <input type="text"/> <input type="text"/>
Subject ID:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Study Code:	Subject ID:	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	Subject initials:	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
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## ELIGIBILITY AND SCREENING

Screening ID     (site code followed by 3 digits visit randomisation number)

### Inclusion Criteria

	Yes <sup>1</sup>	No* <sup>2</sup>
1 Is the subject a healthy adult aged between 18 and 60 years?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
2 Has the subject willingly given written informed consent?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
3 Able and willing to comply with study requirements and follow-up?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>

\*If any inclusion criteria are ticked **NO** then the patient is not eligible for the study.

### Exclusion Criteria

	Yes* <sup>1</sup>	No <sup>2</sup>
1 If female, does the subject is pregnant (based on-site urine test) or lactating?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
2 Have a vaccination schedule within 3 weeks of study duration?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
3 Taken any vaccine in the past 4 weeks?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
4 Taken influenza vaccination in the past 6 months?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
5 Had history of influenza infection in the past 6 months?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
6 Has a serious disease in the opinion of the investigator including, for example: a) cancer, b) heart disease, c) autoimmune disease, d) insulin dependent diabetes mellitus, e) chronic pulmonary disease, f) acute or progressive hepatic disease, g) acute or progressive renal disease?	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>

\*If any exclusion criteria are ticked **YES** then the patient is not eligible for the study.

Is subject eligible?      Yes<sup>1</sup>       No (screen failure)<sup>2</sup>

### If enrolled

Enrollment date (DD/MMM/YYYY)   /    /

Enrollment time (24h format, HH:MM)   :

Subject Initials    (initial of first, middle, last name)

Subject ID     (site code followed by 3 digits treatment allocation randomisation number)

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

Time of informed consent signed (24h format, HH:MM)   :

Eligibility criteria confirmed by

Interviewer name	Signature	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
		Date (DD/MMM/YYYY)

Study Code:

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Subject initials:

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### LABORATORY ANALYSIS

Screening ID

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(site code followed by 3 digits visit randomisation number)

Sample collection date  
(DD/MM/YYYY)

		/				/				
--	--	---	--	--	--	---	--	--	--	--

Sample collection time  
(24h format, HH:MM)

		:		
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Pregnancy test result (Female only)

Positive\* <sup>1</sup>

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Negative <sup>2</sup>

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**\*Positive tested subject is INELIGIBLE**

Done by (staff initials)

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Study Code:

Subject ID:

Subject initials:

### ENROLLMENT (DAY 0)

Enrollment date  
(DD/MMM/YYYY)

 /  / 

### DEMOGRAPHIC DATA

Age:

Birth year (YYYY)

Sex:

Female <sup>1</sup>

Male <sup>2</sup>

Race:

Thai <sup>1</sup>

Asian non-Thai <sup>2</sup>

Other <sup>3</sup>

### MEDICATIONS TAKEN

Is the subject currently or previously taking any medication including OTC, vitamins and/or supplements?

Yes\* <sup>1</sup>

No <sup>2</sup>

\*Record **all** medication on **Concomitant Medications** page

### VITAL SIGNS

Height:

cm

Weight

kg

Body temperature:

°C

Pulse rate

bpm

Blood pressure

/

mmHg

Respiration rate

breaths per minute

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**PHYSICAL EXAMINATION (to be carried out by medical staff only)**

System		Result (check that apply)		Abnormal finding / Details
1	General Appearance	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
2	Abdomen (includes liver and spleen)	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
3	Cardiovascular/ Heart	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
4	Extremities	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
6	Genitourinary	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
7	Head, Ears, Eyes, Nose and Throat	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
8	Lymph Nodes	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
9	Musculoskeletal	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
10	Neck/Thyroid	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
11	Neurological	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
12	Pulmonary/ Chest	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		
13	Skin	Normal <sup>1</sup>		
		Abnormal <sup>2</sup>		
		Not done <sup>3</sup>		

Done by (staff initials)

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### LABORATORY ANALYSIS

Sample collection date  
(DD/MM/YYYY)

		/				/				
--	--	---	--	--	--	---	--	--	--	--

Sample collection time  
(24h format, HH:MM)

		:		
--	--	---	--	--

A/H1N1 Antibody Titer

					IU/mL
--	--	--	--	--	-------

A/H3N2 Antibody Titer

					IU/mL
--	--	--	--	--	-------

B/Yamagata-lineage Antibody Titer

					IU/mL
--	--	--	--	--	-------

B/Victoria-lineage Antibody Titer

					IU/mL
--	--	--	--	--	-------

Done by (staff initials)

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### VACCINATION ADMINISTRATION

Vaccination date  
(DD/MM/YYYY)

		/				/				
--	--	---	--	--	--	---	--	--	--	--

Vaccination time  
(24h format, HH:MM)

		:		
--	--	---	--	--

Vaccination arm

Right <sup>1</sup>

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Left <sup>2</sup>

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Done by (staff initials)

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**CONCOMITANT MEDICATION**

Page number (if extra page is needed)

Last page? Yes <sup>1</sup>  No <sup>2</sup>

Is the subject taking/has taken any other medication since last visit?

Drug name	Start date / time (DD/MMM/YYYY) / (24h, HH:MM)	End date / time (DD/MMM/YYYY) / (24h, HH:MM)	Dose	Unit	Route	Frequency	Reason (put AE/SAE number if associated with AE/SAE)	
	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> Unknown <input type="checkbox"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> On going <input type="checkbox"/>					AE <input type="text"/> #: SAE <input type="text"/> #:	
Key	Unit	<b>Cap</b> (Capsule dosing unit); <b>g</b> (Gram); <b>IU</b> (International Unit); <b>mg</b> (Milligram); <b>mL</b> (Milliliter); <b>Puff</b> (Puff dosing unit); <b>Tab</b> (Tablet dosing unit); <b>ug</b> (Microgram); <b>OTR</b> (Other)						
	Route	<b>1</b> = Intralesional; <b>2</b> = Intramuscular; <b>3</b> = Intraocular; <b>4</b> = Intravenous; <b>5</b> = Nasal; <b>6</b> = Oral; <b>7</b> = Rectal; <b>8</b> = Respiratory (inhalation); <b>9</b> = Subcutaneous; <b>10</b> = Topical; <b>11</b> = Transdermal; <b>12</b> = Other						
	Frequency	<b>BID</b> (Twice per day); <b>PRN</b> (As needed); <b>QD</b> (Daily); <b>QID</b> (4 times per day); <b>QM</b> (Every Month); <b>QOD</b> (Every other day); <b>TID</b> (3 times per day); <b>UNK</b> (Unknown)						