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

CASE RECORD FORM *SCREENING (Day 0, Visit 1)*

Subject ID *(x-xxx)*	Date of screening *(dd/MMM/yyyy)*	Time of screening *(hh:mm 24 hrs)*
___ - ___ ___ ___	__ __/__ __ __/__ __ __ __	____ ____ : ____ ____

Eligibility criteria checklist :

Age : ___ ___ years old	Body temperature : ___ ___ . ___ ___ °C
Pregnancy and lactating status (only for female)	
☐ Pregnant ☐ Not pregnant ☐ Plan to become pregnant during study period	☐ Lactating ☐ N/A (only for male)
Vaccination history	
☐ Received any vaccine **within** 4 weeks ☐ Received any vaccine **longer** than 4 weeks	☐ Never received any vaccine
Vaccination plan	
☐ Plan to receive vaccine **during** 3 weeks after participating the trial ☐ Plan to receive vaccine **after** 3 weeks after participating the trial	☐ No plan to receive vaccine **during** 3 weeks after participating the trial
Influenza vaccination history	
☐ Received influenza vaccine **during** the past 6 months ☐ Received influenza vaccine **longer than** the past 6 months	☐ Never received influenza vaccine
Influenza illness history	
☐ Had influenza illness **during** the past 6 months ☐ Had influenza illness **longer than** the past 6 months	☐ Never had influenza illness

Chronic illness
☐ No chronic illness ☐ Has chronic illness, please specify: _____ _____

Laboratory testing (only for female) :

Urine collection			
Subject ID *(x-xxx)*	Date of collection *(dd/MMM/yyyy)*	Time of collection *(hh: mm 24 hrs)*	Collected by *(Staff initial)*
__ - __ __ __	__ __/__ __ __/__ __ __ __	____ ____ : ____ ____	_____
Pregnancy test result			
☐ Positive ☐ Negative		**Performed by** *(staff initial)* : _____ **Approved by** *(staff initial)* : _____ **Report time** *(hh: mm 24 hr)* : ____ ____ : ____ ____	

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CASE RECORD FORM *ENROLLMENT (Day 0, Visit 1)*

Subject ID *(x-xxx)*	Date of enrollment *(dd/MMM/yyyy)*	Time of enrollment *(hh:mm 24 hrs)*
___ - ___ ___ ___	__ __/__ __ __/__ __ __ __	____ ____ : ____ ____

Personal identifying information/ demographic data :

Age : ___ ___ years old	Sex : ☐ Male ☐ Female
Date of birth *(dd/MMM/yyyy)* : ___ ___/___ ___ ___/___ ___ ___ ___	Emergency contact information : _____ _____

Informed consent form :

Start time *(24 hrs)* : ____ ____ : ____ ____	End time *(24 hrs)* : ____ ____ : ____ ____
ICF signed date *(dd/MMM/yyyy)* : ___ ___/___ ___ ___/___ ___ ___ ___	
Performed by *(staff initial)* : _____	

Physical examination :

Weight : ___ ___ . ___ ___ kg	Height : ___ ___ ___ . ___ ___ cm
Blood pressure : _____/_____ mmHg	Respiratory rate : _____ /min
Heart rate : _____ /min	Body temperature : ___ ___ - ___ ___ °C
☐ Pregnant ☐ Not pregnant ☐ Plan to become pregnant during study period	☐ Lactating ☐ N/A (only for male)
Performed by *(staff initial)* : _____	

Past medical history :

Vaccination history	
☐ Received any vaccine **within** 4 weeks ☐ Received any vaccine **longer than** 4 weeks	☐ Never received any vaccine
Vaccination plan	
☐ Plan to receive vaccine **during** 3 weeks after participating the trial ☐ Plan to receive vaccine **after** 3 weeks after participating the trial	☐ No plan to receive vaccine **for** 3 weeks after participating the trial
Influenza vaccination history	
☐ Received influenza vaccine **during** the past 6 months ☐ Received influenza vaccine **longer than** the past 6 months	☐ Never received influenza vaccine
Influenza illness history	
☐ Had influenza illness **during** the past 6 months ☐ Had influenza illness **longer than** the past 6 months	☐ Never had influenza illness

Is participant eligible to participate in the study :

☐ Yes ☐ No	
Study physician *(staff initial)* : _____	**Research nurse** *(staff initial)* : _____

Laboratory testing :

Blood collection			
Subject ID *(x-xxx)*	**Date of collection** *(dd/MMM/yyyy)*	**Time of collection** *(hh: mm 24 hrs)*	**Collected by** *(Staff initial)*
___ - ___ ___ ___	__ __/__ __ __/__ __ __ __	____ ____ : ____ ____	_____
Geometric Mean Titers (GMTs) as baseline before vaccination result			
_____	**Performed by** *(staff initial)* : _____ **Approved by** *(staff initial)* : _____ **Report time** *(hh: mm 24 hr)* : ____ ____ : ____ ____		

Influenza Hemagglutination Inhibition (HAI) titer as baseline before vaccination result	
_____	Performed by *(staff initial)* : _____ Approved by *(staff initial)* : _____ Report time *(hh: mm 24 hr)* : ____ ____ : ____ ____

Study participant was randomized to received :

☐ Quadrivalent influenza vaccine; QIV ☐ Trivalent influenza vaccine; TIV

Study vaccine preparation and administration :

Vaccine information		
Kit number	Lot number	Expiry date *(dd/MMM/yyyy)*
_____	_____	__ __/__ __ __/__ __ __ __
Prepared by *(staff initial)* : _____		

Vaccine administration		
Date of administration *(dd/MMM/yyyy)*	Time of administration *(hh: mm 24 hr)*	Injection site *(Left or right upper arm)*
__ __/__ __ __/__ __ __ __	____ ____ : ____ ____	_____
Injected/Performed by *(staff initial)* : _____		

Post injection reaction (check all that apply) :

Solicited local (Injection site) reactions		
☐ Pain ☐ Induration	☐ Redness ☐ Swelling	☐ Ecchymosis (injection site bruising)
Solicited systemic reactions		
☐ Fever ($\geq$ 38 °C) ☐ Myalgia	☐ Headache ☐ Shivering	☐ Malaise
Observed by (staff initial) : _____ Date : __ __/__ __ __/__ __ __ __ Time : ___ ___ : ___ ___		

Diary card provided : ☐ Yes ☐ No Provided by *(staff initial)* : _____