

CASE REPORT FORM	Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years	SCREENING (VISIT1)
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Identifier

Site - Subject ID ____ - _____	Date of visit ____/____/_____ (DD/MM/YYYY)
Date of informed consent signed ____/____/_____ (DD/MM/YYYY)	

Eligibility Criteria

The participant who meet any of the following criteria will be excluded from the study.

Exclusion criteria	Yes	No	Unsure
1. The participant's age is less than 18 years or more than 60 years on the date of visit	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
2. The participant is pregnant or lactating	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
3. The participant intends to become pregnant during the next 3 weeks	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
4. The participant received any vaccine in the past 4 weeks	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
5. The participant plans to receive vaccine during the next 3 weeks	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
6. The participant receives influenza vaccine in the past 6 months	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
7. The participant has had influenza illness in the past 6 months	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
8. The participant's body temperature is equal to or higher than 38.0°C	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉
9. The participant has chronic illness that might interfere with trial conduct or completion or would increase the risk to the individual by participating in this study	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉

Is the participant eligible to take part in this study ₁ Yes ₂ No

Laboratory

Pregnancy test <input type="checkbox"/> ₁ Positive <input type="checkbox"/> ₉ Not done <input type="checkbox"/> ₂ Negative
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CASE REPORT FORM	Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years	ENROLLMENT (VISIT1)
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Identifier

Site - Subject ID ____ - _____	Date of visit ____/____/_____ (DD/MM/YYYY)
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Demographics

Sex <input type="checkbox"/> ₁ Male <input type="checkbox"/> ₂ Female	Date of birth ____/____/_____ (DD/MM/YYYY)	Age ____ years ____ months
Race <input type="checkbox"/> ₁ Asian <input type="checkbox"/> ₂ White	<input type="checkbox"/> ₃ African American <input type="checkbox"/> ₄ American Indian or Alaska Native	<input type="checkbox"/> ₅ Native Hawaiian or Other Pacific Islander

Physical Examination

Weight (kg) ____.	Height (cm) ____.
Body temperature (°C) ____.	BP (mmHg) ____ (systolic) ____ (diastolic)
Heart rate (beats/min) ____	Respiratory rate (breaths/min) ____

Please check the appropriate box for each system.

Review by systems	Normal	Abnormal	Not done	Comments
1. HEENT	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
2. Cardiovascular	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
3. Chest	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
4. Abdomen	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
5. Musculoskeletal	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
6. Neurological	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	
7. Other body systems	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₉	

Vaccination

Is the participant eligible to take part in this study <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Vaccination <input type="checkbox"/> ₁ QIV <input type="checkbox"/> ₂ TIV
Date of vaccination ____/____/_____ (DD/MM/YYYY)	Time of vaccination ____ : ____ (HH:MM) [24 hrs]

Laboratory

Date of sample collection ____/____/_____ (DD/MM/YYYY)	Time of sample collection ____ : ____ (HH:MM) [24 hrs]
A/H1N1 Antibody titer ____ : ____	A/H3N2 Antibody titer ____ : ____
B/Yamagata Antibody titer ____ : ____	

Solicited Reaction

Pain <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Fever <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
Redness <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Headache <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
Swelling <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Malaise <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
Induration <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Shivering <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
Ecchymosis <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	Other <input type="checkbox"/> ₁ Yes _____ <input type="checkbox"/> ₂ No