

Study Code:

Randomization no:

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Subject initials:

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Screen ID:

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Eligibility Criteria

Inclusion Criteria	Yes	No
1. Aged 18 to 60 years on the day of inclusion		
2. Able to provide written informed consent prior to any study procedure		
3. For female participants, must have negative urine pregnancy test at enrollment and willing to take reliable birth control measures for 1 month after vaccination		
4. Able to attend all scheduled visits and to comply with all trial procedures		
Exclusion Criteria	Yes	No
Volunteers with ANY of the following criteria at screening will not be eligible for participation		
1. Pregnant, lactating women or female who intends to become pregnant during the study period		
2. Receipt of any vaccine during the 4 weeks preceding the trial vaccination or planned receipt of any vaccine during the 3 weeks following the trial vaccination		
3. Vaccination against influenza (in a clinical trial or a flu vaccination campaign) or self-reported history of influenza infection (having influenza-like illness) in the past 6 months		
4. Febrile illness (body temperature $\geq 38.0^{\circ}\text{C}$) on the day of vaccination (temporary exclusion, a prospective participant should not be included in the study until the febrile event has subsided)		
5. Chronic illness that, in the opinion of the investigator, is at a stage where it might interfere with trial conduct or completion or would increase the risk to the individual by participating in this study		

Is the participant eligible to take part in this study?

Yes

No

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INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place or any current therapy is discontinued for the purposes of participation in this study.

Has the subject freely given written informed consent?

Yes No

Date of Informed Consent Form Signed

DD / MM / YYYY

Time of Informed Consent ____: ____ (24 hours)

Random ID:

Demographic

Date of Visit: / / (DD/MM/YYYY)

Year of Birth:

Sex: Male Male

Vital Signs

Height: Centimeter

Weight: Kilogram

Systolic Blood Pressure: mmHg

Diastolic Blood Pressure: mmHg

Pulse Rate: beats per minute

Respiratory Rate: breaths per minute

Body Temperature: °C

Physical Examination	Normal	Abnormal	Not Done	Comments
HEENT				
Cardiovascular				
Chest				
Abdomen				
Musculoskeletal				
Neurological				
Other Body System				

Urine Pregnancy Test: Positive Negative N/A

Physician Sign _____ Time ____: ____ (24 hours)

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Laboratory

Date of Sample Collection: / / (DD/MM/YYYY)

Time of Sample Collection: ___ : ___ (24 hours)

A/H1N1 Antibody Titer: A/H3N2 Antibody Titer:

B/Yamagata-lineage Antibody Titer: B/Victoria-lineage Antibody Titer:

Vaccine Administration

Date of Vaccination: / / (DD/MM/YYYY)

Time of Vaccination: ___ : ___ (24 hours)

Injection Site: Intramuscular left arm Intramuscular right arm
 N/A Other specify _____

Side Effect After Vaccination (observe 30 min)
 No Yes, specify _____

Physician Sign _____

Time ___ : ___ (24 hours)