

Study Visit: Screening

Screening demographic

 - -
Subject ID (Screening number)

Should be enter in A/B – XXXX format

Example: A-123

 -
Body Temperature
 . Celsius

Subject Age
 years

Sex
 Male

 Female

Birth control:
 Yes

 Oral contraceptives

 Implant

 Transdermal patch

 No

Lactating:
 Yes No

Laboratory Test

Urine Pregnancy test
 Positive Negative Not done

Eligibility Criteria *Check in the box if the subject meets the criteria*

Inclusion Criteria		
Yes	No	
		Aged 18 to 60 years on the day of inclusion
		Able to provide written informed consent prior to any study procedure
		For female participants , must have negative urine pregnancy test at enrollment and willing to take reliable birth control measures for 1 month after vaccination
		Able to attend all scheduled visits and to comply with all trial procedures
Exclusion Criteria		
Yes	No	
		Pregnant, lactating women or female who intends to become pregnant during the study period
		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
		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
		Febrile illness (body temperature $\geq 38.0^{\circ}\text{C}$) on the day of vaccination
		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
Subject is eligible for participating in study		<input type="checkbox"/> Yes <input type="checkbox"/> No

Study Visit: Enrollment Subject Data

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Subject Randomization Number

Should be enter in XXX-XX format

Example: 123-45

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Randomization Group

- Trivalent Influenza Vaccine (TIV)
- Quadrivalent Influenza Vaccine (QIV)

Laboratory Test

Blood Collection for Pre-dose HAI Titer

- Done
- Not done

Time of time collection

Enter in 24 hr. format

:

Result:

HAI Titer

Enter in ratio format

Example: 1:40

:

Vaccine Administration

Time of vaccine administration

Enter in 24 hr. format

:

Quantity of vaccine

. mL

Type of Vaccine Administered

- Trivalent Influenza Vaccine (TIV)
- Quadrivalent Influenza Vaccine (QIV)