Case Report Form Protocol No.: QUADRIFLU	**Visit 1 (Day 0) Screening**	Site No. □□□ Site - Subject Screening No. S □□□ - □□□

Visit Date

Date of Visit	□□ - □□□ - □□□□	(DD – MMM – YYYY)

Demography

Was informed consent signed?	□ Yes	□ No
Informed Consent Date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Year of Birth	□□□□	A.D.
Gender	□ Male	□ Female
Age		*(Auto – calculated from year of birth)*

Eligibility

Inclusion Criteria (A subject will be eligible for inclusion if ALL the following criteria are met.)

1	Aged 18 to 60 years on the day of inclusion	□ Yes	□ No
2	Able to provide written informed consent prior to any study procedure	□ Yes	□ No
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	□ Yes	□ No
4	Able to attend all scheduled visits and to comply with all trial procedures	□ Yes	□ No

Exclusion Criteria (A subject with ANY of the following criteria will not be eligible for participation)

1	Pregnant, lactating women or female who intends to become pregnant during the study period	□ Yes	□ No
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	□ Yes	□ No
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	□ Yes	□ No
4	Febrile illness (body temperature ≥ 38.0°C) on the day of vaccination (temporary exclusion, a prospective participant should not be included in the study until the febrile event has subsided)	□ Yes	□ No
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.	□ Yes	□ No

Assessment of Eligibility

Is the subject eligible to participate in the study? □ Yes □ No

If "No", please select the reason for screening fail.
□ Inappropriate Inclusion/Exclusion Criteria
□ Withdrawal of Consent
□ Investigator's discretion
□ Others _____

Laboratory

Urine Pregnancy Test

(Please conduct to women of childbearing age)

Was urine pregnancy test performed?
□ Yes
□ No (Male or Non-fertile female)
Please specify details: _____

Sample collection date □□ - □□□ - □□□□ (DD – MMM – YYYY)

Sample collection time □□ : □□ HH : MM

Results □ Positive □ Negative

Birth Control Method (Select all that apply)
□ Condom
□ Oral Contraception
□ Intrauterine contraceptive device
□ Injectable or implantable contraceptive
□ Others, _____

Medical History

Has subject had any medical conditions/ chronic illness? □ Yes □ No

If "Yes", please complete Medical History Form.

Prior Concomitant Medication

Prior Vaccination

Any previous vaccination within 4 weeks (except influenza)?	□ Yes	□ No
If "Yes" Name of previous vaccination	_____	
Date of previous vaccination	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Any influenza vaccine in the past 6 months?	□ Yes	□ No
If "Yes" Date of influenza vaccination	□□ - □□□ - □□□□	(DD – MMM – YYYY)

Prior Medication

Any prior medication taken or ongoing at visit? *If "Yes", please complete Concomitant Medication Form.*	□ Yes	□ No

Physical Examination

Was physical examination performed? □ Yes □ No

If No, please provide reason _____

Date of Physical Examination □□ - □□□ - □□□□ (DD – MMM – YYYY)

Time of Physical Examination □□ : □□ HH : MM

Examination	Results	If abnormal, clinically significant, please specify details.
General Appearance	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
EENT	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Lung	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Heart	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Abdomen	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Skin	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Lymph node	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	

Extremities	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Back	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Neurological / Vascular	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	
Other, specify _____	□ Normal □ Abnormal, Clinically Significant □ Abnormal, Not Clinically Significant □ Not Examine	

Vital Sign

Was vital sign measured? □ Yes □ No

If No, please provide reason _____

Time of Vital Sign Measurement □□ : □□ HH : MM

Position of subject during measurement
□ Sitting
□ Standing
□ Supine

Measurements	**Results**	**Formats**	**Units**
Weight		(xx.x)	Kg
Height		(xxx.x)	Cm
Body Temperature		(xx.x)	°C
Systolic Blood Pressure		(xxx)	mmHg
Diastolic Blood Pressure		(xxx)	mmHg
Heart Rate		(xxx)	Beats per minute
Respiratory Rate		(xx)	Breaths per minute
Oxygen saturation		(xxx)	%

Case Report Form Protocol No.: QUADRIFLU	**Visit 1 (Day 0) Enrolment**	Site No. □□□ Site - Subject Random No. R □□□ - □□□

Laboratory

Blood Test

Was blood sample collected?	□ Yes	□ No
Sample collection date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Sample collection time	□□ : □□	HH : MM
Volume of blood sample taken	_____	mL

Test Name	Result
A/H1N1 Antibody Titer	
A/H3N2 Antibody Titer	
B/Yamagata-lineage Antibody Titer	
B/Victoria-lineage Antibody Titer	

Vaccination (Unblinded)

This is only visible for unblinded staff, injection nurse, or pharmacist

Randomization No.	_____	
Assigned vaccine	• QIV (Quadrivalent inactivated influenza vaccine)	• TIV (Trivalent influenza vaccine) (Control group)

Vaccination (Blinded)

Injection Site	□ Left arm	□ Right arm
Injection Dose	_____	mL
Route of administration	□ IM □ SC □ Other	If Other, please specify _____
Injection Date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Injection Time	□□ : □□	HH : MM

Case Report Form Protocol No.: QUADRIFLU	**Cumulative Form**	Site No. □□□ Site - Subject Random No. R □□□ - □□□

Cumulative Form (Can be repeated)

Medical History

Medical Condition ID	(Auto-generate number in sequence)	
Medical Condition		
Start date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Ongoing	□ Yes	□ No
End date	□□ - □□□ - □□□□	(DD – MMM – YYYY)

Cumulative Form (Can be repeated)

Prior Concomitant Medication

Medication ID	(Auto-generate number in sequence)	
Medication name		
Dose		Dose Unit: [Dropdown list][1]
Dosage Form	[Dropdown list][2]	
Frequency	[Dropdown list][3]	
Route of Administration	[Dropdown list][4]	
Indication		
Start date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Ongoing	□ Yes	□ No
End date	□□ - □□□ - □□□□	(DD – MMM – YYYY)
Reason for use	□ Medical History □ Adverse Event □ Supplement □ Other: _____	

[Dropdown list]

Dose Unit[1]
1- G
2- Mg
3- µg
4- L
5- mL
6- IU
7- Other

Dosage Form[2]
1- Tablet
2- Capsule
3- Ointment
4- Cream
5- Suppository
6- Spray
7- Suspension
8- Solution
9- Implant
10- Other

Frequency[3]
1- OD
2- BID
3- TID
4- PRN
5- QOD
6- Weekly
7- Monthly
8- Other

Route of Administration[4]
1- Oral
2- Topical
3- SC
4- IM
5- IV
6- Nasal
7- Vaginal
8- Rectal
9- Other