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

SCREENING FORM

Site ID	Patient No.	Initials

General instruction: Put ”X” on boxes requiring choices (example: ☒)

S1	Age	☐☐☐ years old
S2	Sex	☐ Male ☐ Female
S3	Pregnancy/ Lactating status	☐ Pregnant or lactating or both ☐ Not pregnant nor lactating nor both, but planning to conceive within the next month ☐ Not sure ☐ Not applicable
S3.1	Result of pregnancy laboratory test	☐ Positive ☐ Negative ☐ Not applicable
S4	Receipt of any vaccine	☐ Received any vaccine during the 4 weeks BEFORE the trial ☐ Planning to receive any vaccine during 3 weeks AFTER the trial ☐ Did not receive any vaccine during 4 weeks before trial nor plans to receive any vaccine 3 weeks after the trial
S5	Vaccination against influenza status	☐ Had influenza vaccination in the past 6 months ☐ Did not receive influenza vaccination in the past 6 months
S6	History of influenza infection	☐ Did have any symptoms in the past 6 months (put “X” whenever applies): ☐ Fever (>37.9 degrees Celsius) ☐ Colds ☐ Cough ☐ Body pain/ Fatigue ☐ Nausea/ Headache ☐ Did not have any influenza-like symptoms in the past 6 months
S7	Chronic illness	Do you have any chronic illness?

			Yes, please specify (put “X” whenever applies): ☐ Diabetes mellitus ☐ Hypertension ☐ Chronic kidney disease ☐ Cardiovascular disease ☐ Others, please specify: _____
			No

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ENROLLMENT FORM

Site ID	Enrollment No.	Initials

General instruction: Put "X" on boxes requiring choices (example: ☒)

E1	Date of visit	☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY (eg. 01-JAN-1999)	
E2	Date of informed consent form signed	☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY (eg. 01-JAN-1999)	
E3	Time of informed consent signed	☐☐:☐☐ 24-hour format (eg. 13:00 for 1:00 PM)	
DEMOGRAPHIC CHARACTERISTICS			
E4	Year of birth	☐☐☐☐ (eg. 1999)	
E5	Sex	☐ Male ☐ Female	
E6	Race	☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Not reported ☐ Unknown ☐ Other, please specify: _____	
VITAL SIGNS			
E7	Height	Value: _____	Unit: ☐ Foot, inches (eg, 5'4") ☐ Centimeters
E8	Weight	Value: _____	Unit: ☐ Pounds ☐ Centimeters
E9	Blood pressure (BP)	Diastolic BP _____ mmHg	Systolic BP _____ mmHg
E10	Pulse rate	Value:	

		_____ per minute	
E11	Respiration rate	Value: _____ per minute	
E12	Body temperature	Value: _____	Unit: ☐ Celsius ☐ Fahrenheit
PHYSICAL EXAM			
E13	HEENT	☐ With findings, please specify: _____ ☐ Normal	
E14	Cardiovascular	☐ With findings, please specify: _____ ☐ Normal	
E15	Chest	☐ With findings, please specify: _____ ☐ Normal	
E16	Abdomen	☐ With findings, please specify: _____ ☐ Normal	
E17	Musculoskeletal	☐ With findings, please specify: _____ ☐ Normal	
E18	Neurological	☐ With findings, please specify: _____ ☐ Normal	

E19	Other body system	☐	Body system with findings: _____ Findings, please specify: _____
		☐	Not applicable

E20. ELIGIBILITY CHECK

Put "X" on choice (example: ☒)

Is the participant eligible to take part in this study?

☐	☐
NO *Stop, do not proceed.*	YES *Proceed to next items*

LABORATORY			
E21	Date of sample collection	☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY (eg. 01-JAN-1999)	
E22	Time of sample collection	☐☐:☐☐ 24-hour format (eg. 13:00 for 1:00 PM)	
E23	A/H1N1 Antibody Titer	Baseline value: _____	Unit: _____ For units measured in micro, use "mcg" notation to avoid confusion with "mm" for milli units.
E24	A/H3N2 Antibody Titer	Baseline value: _____	Unit: _____

Commented [AJO1]: For the titers, I did not provide choices as there are lots of combinations in terms of units.

			For units measured in micro, use “mcg” notation to avoid confusion with “mm” for milli units.
E25	B/Yamagata-lineage Antibody Titer	Baseline value: _____	Unit: _____ For units measured in micro, use “mcg” notation to avoid confusion with “mm” for milli units.
E26	B/Victoria-lineage Antibody Titer	Baseline value: _____	Unit: _____ For units measured in micro, use “mcg” notation to avoid confusion with “mm” for milli units.
VACCINE ADMINISTRATION			
E27	Date of vaccination	| | | - | | | | - | | | | | DD-MMM-YYYY (eg. 01-JAN-1999)	
E28	Time of vaccination	| | | : | | | 24-hour format (eg. 13:00 for 1:00 PM)	
E29	Vaccination arm	| | Left | | | Right |	

--- NOTHING FOLLOWS ---

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