Week 2 Assignment 1 : CRF Design

According to the "QUADRIFLU" project, you have designed the data including visits, domains, and variables to be collected in the study. *Please design a Case Record Form (CRF) only for "Screening" and "Enrollment" visits* according to domains and variables defined in the first week. (Here is revised version of variables part screening and enrollment)

Visits	Domain	Variables	
	Identifier	 ScreenID Site No Initials 	
		Date of screening Age	
Screening	Eligibility Criteria	 Pregnant or lactating Receive any vaccine within 4 weeks preceding the trial Plan to receive vaccine during 3 weeks following the trial Received influenza vaccine in the past 6 months Had influenza illness in the past 6 months Chronic illness History of anaphylactic reaction to previous influenza vaccine History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine Current medication of immunosuppressive agents Bleeding disorders or current anticoagulant/antiplatelet drug use 	
	Laboratory	Pregnancy test	
	Screening Criteria	Does participant meet the criteria for study	
	Identifier	Random ID	
	Demographics	 Date of visit Date of informed Consent Form Signed Time of informed consent form signed Year of Birth Sex (biologically determined) Race/ethnicity 	
Enrollment VISIT1(day0)	Vital signs	 Height (cm) Weight (kg) BMI (calculated) Blood pressure (mmHg) Heart rate (bpm), Respiratory rate (breath/min) Body Temperature (°C) 	
	Physical Examination	 HEENT CVS Chest Abdomen MSK Neurological Review of other system 	
	Eligible check	Is participant eligible to take part in the study	
	Laboratory	 Date of sample collection Time of sample collection 	

	•	A/H1N1 Antibody titer A/H3N1 Antibody Titer B/Yamagata-lineage Antibody Titer B/Victoria-lineage Antibody Titer
Vaccine administration	•	Date of Vaccination Time of vaccination Type of vaccine received; QIV, TIV

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years						
CRI	CRF01 Screening Form					
Site	Site No. Screening ID Initials Date of Screening					
Eligi	ble Criteria					
1	Aged between 18 and 60 years old on the day of screening	☐ Yes	$\square_{\scriptscriptstyle 0}$ No			
2	Able to provide written informed consent prior to any study procedure	☐ Yes	$\square_{\scriptscriptstyle 0}$ No			
3	Pregnancy (for male, please check "NA")	□ ₀ Yes	□ No	□NA		
4	Willing to take reliable birth control measures for 1 month after vaccination (for male, please check "NA")	☐ Yes	$\square_{\scriptscriptstyle 0}$ No	□NA		
5	Lactating (for male, please check "NA")	□ ₀ Yes	□ No	□NA		
6	Receive any vaccine within 4 weeks preceding the trial	□ ₀ Yes	□ No			
7	Plan to receive vaccine during 3 weeks following the trial	□ ₀ Yes	□ No			
8	8 Vaccination against influenza in the past 6 months \square_0 Yes \square No					
9	9 Self-reported history of influenza infection in the past 6 months \square_0 Yes \square No					
10	0 Chronic illness that might interfere with the trial or increase participant risk □ ₀ Yes □ No					
11	History of anaphylactic reaction to previous influenza vaccine					
12	History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine					
13	Current medication of immunosuppressive agents					
14	4 Bleeding disorders or current anticoagulant/antiplatelet drug use ☐ Yes ☐ No					
15	5 Able to attend all scheduled visits and comply with all procedures					
Laboratory						
16	16 Urine Pregnancy test (for male, please check "NA") □ ₀ Positive □ Negative □ NA					
Screening Result						
17	17 Is participant eligible for criteria (<i>Check No, if any checkbox</i> \square_0 in this form) \square Yes \square No					
18	18 Assigned Random ID					

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years					
CRF02 Enrollment Form					
Site	No. Random ID.	Initials	Date of visit		
			day month year		
Dem	nographic	1			
4		Date of Informed Consent Fo	orm Signed Time of Informed Consent Form Signed (24-hr Format)		
1	Informed Consent	day month year	hour minute		
2	Year of Birth				
3	Sex (biologically de	termined)	☐ Male ☐ Female		
		☐ Asian ☐ Am	erican Indian or Alaska Native		
4	Race	☐ White ☐ Bla	ck or African American		
		Other, specify			
Vital	l Signs	1			
5	Height		cm		
6	Weight		kg		
7	Blood pressure		Systolic Diastolic mmHg		
8	Pulse Rate		beats per minute		
9	Respiratory rate		times per minute		
10	Body Temperature		°C		
Physical Examination					
11	HEENT		□ Normal □ Abnormal, specify		
12	Cardiovascular		□ Normal □ Abnormal, specify		
13	Chest		□ Normal □ Abnormal, specify		
14	Abdomen		□ Normal □ Abnormal, specify		

15	Musculoskeletal		☐ Normal	☐ Abnormal, specify	
16	Neurological		☐ Normal	☐ Abnormal, specify	
17	Review of other Bod	y system	☐ Normal	☐ Abnormal, specify	
Eligi	Eligible Check				
18	Is the participant elig	ible to take part in this study	☐ Yes	\square No	
Labo	oratory				
		Date of Sample Collection		Time of Sample Collection (24-hr Format)	
19	Laboratory	day month year		hour minute	
20	A/H1N1 Antibody Tite	er			
21	A/H3N1 Antibody Tite	er			
22	B/Yamagata-lineage	Antibody Titer			
23	B/Victoria-lineage A	ntibody Titier			
Vaccine Administration					
	Vaccination	Date of vaccination		Time of vaccination (24-hr Format)	
24		day month year		hour minute	
25	5 Vaccination Arm		QIV	□ TIV	

Note: After I uploaded the assignment in pdf, the check box symbol didn't show up in the form, so I re-upload again in word document and add another page of CRF in picture just in case.

S10	S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years				
CRI	CRF01 Screening Form				
Site	No. Screening ID Initials Date of Screening				
	day month year				
Eligi	ble Criteria				
1	Aged between 18 and 60 years old on the day of screening	☐ Yes	\square_0 No		
2	Able to provide written informed consent prior to any study procedure	☐ Yes	\square_0 No		
3	Pregnancy (for male, please check "NA")	□₀ Yes	□ No	□NA	
4	Willing to take reliable birth control measures for 1 month after vaccination (for male, please check "NA")	☐ Yes	□₀ No	\square NA	
5	Lactating (for male, please check "NA")	□₀Yes	\square No	\square NA	
6	6 Receive any vaccine within 4 weeks preceding the trial □₀ Yes □ No				
7	7 Plan to receive vaccine during 3 weeks following the trial \$ \Boxed{\square}_0\$ Yes \$ \text{No}\$				
8	Vaccination against influenza in the past 6 months	□₀Yes	□ No		
9 Self-reported history of influenza infection in the past 6 months			□ No		
10	10 Chronic illness that might interfere with the trial or increase participant risk □₀ Yes □ No				
11	History of anaphylactic reaction to previous influenza vaccine	□₀Yes	□ No		
12	History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine				
13	Current medication of immunosuppressive agents	☐ Yes	□ No		
14	14 Bleeding disorders or current anticoagulant/antiplatelet drug use				
15	15 Able to attend all scheduled visits and comply with all procedures ☐ Yes ☐ No				
Laboratory					
16	and the grantery test (the shade) process that y				
Screening Result					
17	17 Is participant eligible for criteria (<i>Check No, if any checkbox</i> □₀ in this form) □ Yes □ No				
18	18 Assigned Random ID				

12 Cardiovascular Normal Abnormal, specify 13 Chest Normal Abnormal, specify 14 Abdomen Normal Abnormal, specify 15 Musculoskeletal Normal Abnormal, specify	S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years						
Demographic Date of Informed Consent Form Signed Date of Informed Consent Form Signed Date of Informed Consent Form Signed Time of Informed Consent Form Signed (24-fir Format)	CRI	CRF02 Enrollment Form					
Demographic Informed Consent Date of Informed Consent Form Signed Time of Informed Consent Form Signed (24-hr Format)	Site	No. Random ID.	Initials	Date of visit			
Informed Consent Date of Informed Consent Form Signed Time of Informed Consent Form Signed (24-hr Format) Informed Consent Formation Information Informed Consent Formation Information Informed Consent Formation Information Info				day month year			
Informed Consent	Den	nographic					
2 Year of Birth			Date of Informed Consent Fo	orm Signed Time of Informed Consent Form Signed (24-hr Format)			
Sex (biologically determined)	1	Informed Consent	day month year	hour : ininute			
Asian	2	Year of Birth					
Vital Signs Other, specify Other, specify Other, specify Other, specify Other Specify	3	Sex (biologically de	termined)	☐ Male ☐ Female			
Other, specify Other, specify Other, specify Other O			☐ Asian ☐ Am	nerican Indian or Alaska Native $\ \square$ Native Hawaiian or Other Pacific Islander			
Vital Signs S Height	4	Race	☐ White ☐ Bla	ack or African American			
S Height			☐ Other, specify				
Blood pressure	Vita	Signs					
Systolic mmHg Diastolic mmHg	5	Height		cm			
8 Pulse Rate	6	Weight		kg			
generatory rate times per minute times p	7	Blood pressure		Systolic Diastolic mmHg			
Body Temperature	8	Pulse Rate		beats per minute			
Physical Examination 11 HEENT	9	Respiratory rate		times per minute			
HEENT	10	Body Temperature		°c			
12 Cardiovascular	Phy	sical Examination					
13 Chest	11	HEENT		□ Normal □ Abnormal, specify			
Abdomen	12	Cardiovascular		□ Normal □ Abnormal, specify			
Musculoskeletal	13	Chest		□ Normal □ Abnormal, specify			
15 Musculoskeletal	14	Abdomen		□ Normal □ Abnormal, specify			
Review of other Body system	15	Musculoskeletal					
Eligible Check 18 Is the participant eligible to take part in this study Yes No Laboratory 19 Laboratory Date of Sample Collection Time of Sample Collection (24-hr Format) 20 A/H1N1 Antibody Titer 21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titier Vaccine Administration Date of vaccination Time of vaccination (24-hr Format)	16	Neurological		□ Normal □ Abnormal, specify			
18 Is the participant eligible to take part in this study Yes No	17	Review of other Bod	ly system	□ Normal □ Abnormal, specify			
Laboratory Date of Sample Collection Time of Sample Collection (24-hr Format) 20 A/H1N1 Antibody Titer 21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titer Vaccine Administration Date of vaccination Date of vaccination Time of vaccination (24-hr Format) Time of vaccination (24-hr Format) Time of vaccination (24-hr Format)	Eligi	ble Check					
Date of Sample Collection Time of Sample Collection (24-hr Format) 20 A/H1N1 Antibody Titer 21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titer Vaccine Administration Date of vaccination Time of Sample Collection (24-hr Format) Implicit Implinition Implicit Implicit Implicit Implicit Implicit Implicit Impl	18	Is the participant elig	gible to take part in this study	☐ Yes ☐ No			
19 Laboratory 20 A/H1N1 Antibody Titer 21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titer Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Time of vaccination (24-hr Format)	Lab	Laboratory					
20 A/H1N1 Antibody Titer 21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titier Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Time of vaccination (24-hr Format)			Date of Sample Collection	Time of Sample Collection (24-hr Format)			
21 A/H3N1 Antibody Titer 22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titier Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Vaccination	19	Laboratory	day month year	hour : minute			
22 B/Yamagata-lineage Antibody Titer 23 B/Victoria-lineage Antibody Titier Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Vaccination	20	A/H1N1 Antibody Tit	er				
23 B/Victoria-lineage Antibody Titier Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Aday month year hour minute	21	A/H3N1 Antibody Tit	er				
Vaccine Administration Date of vaccination Time of vaccination (24-hr Format) Aday month year hour minute	22	B/Yamagata-lineage	e Antibody Titer				
Date of vaccination Time of vaccination (24-hr Format) Vaccination Date of vaccination (24-hr Format) I hour minute	23	B/Victoria-lineage A	ntibody Titier				
24 Vaccination	Vac	Vaccine Administration					
	24	Vaccination					
	25	Vaccination Arm	, , , , , , , , , , , , , , , , , , , ,				