Form: Participant Identifier

Participant ID: _____

Form: Screening Date of Visit

Screening visit date	_____
Was this participant originally screened for Cohort 1 or Cohort 2?	Cohort 1 ☐ Cohort 2 ☐
If Cohort 1, Select Group	1E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273 booster ☐ 2E: Previously dosed Moderna – mRNA-1273; Moderna – mRNA-1273 booster ☐ 3E: Previously dosed Pfizer/BioNTech – BNT162b2; Moderna – mRNA-1273 booster ☐ 4E: Previously dosed Janssen – Ad26.COV2-S; Janssen – Ad26.COV2-S booster ☐ 5E: Previously dosed Moderna – mRNA-1273; Janssen – Ad26.COV2-S booster ☐ 6E: Previously dosed Pfizer/BioNTech – BNT162b2; Janssen – Ad26.COV2-S booster ☐ 7E: Previously dosed Janssen – Ad26.COV2-S; Pfizer/BioNTech – BNT162b2 booster ☐ 8E: Previously dosed Moderna – mRNA-1273; Pfizer/BioNTech – BNT162b2 booster ☐ 9E: Previously dosed Pfizer/BioNTech – mRNA-BNT162b2; Pfizer/BioNTech – BNT162b2 booster ☐ 10E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273.211 booster ☐ 11E: Previously dosed Pfizer/BioNTech – BNT162b2; Moderna – mRNA-1273.211 booster ☐ 12E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273 50 mcg dose booster ☐ 13E: Previously dosed Moderna – mRNA-1273; Moderna – mRNA-1273 50 mcg dose booster ☐ 14E: Previously dosed Pfizer/BioNTech –BNT162b2; Moderna – mRNA-1273 50 mcg dose booster ☐ 15E: Previously dosed Janssen – Ad26.COV2-S; Novavax – NVX-CoV2373 booster ☐ 16E: Previously dosed Moderna – mRNA-1273; Novavax – NVX-CoV2373 booster ☐

Form: Screening Date of Visit

17E: Previously dosed Pfizer/BioNTech –BNT162b2; Novavax – NVX-CoV2373 booster	☐

Form: Interim Visit Summary

Visit date	_____
Interim visit code	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new medical conditions/events reported at this visit?	Yes ☐ No ☐
If "Yes", update the Medical History Log CRF.	
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Reason for interim visit (Select all that apply.)	
AE report or follow-up	☐
Completion of missed visit procedures	☐
If completion of missed visit procedures, for which visit are procedures being made up?	V1 - Screening/Enrollment - C1/C2 ☐ V2 - Day 8 - Phone Visit - C1 ☐ V3 - Day 15 - C1 ☐ V4 - Day 29 - C1 ☐ V5 - Day 91 - C1 ☐ V6 - Day 181 - C1 ☐ V7 - Day 366 - C1 ☐ V102 - Day 8 - Phone Visit - C2 ☐ V103 - Day 29 - C2 ☐ V104 - Day 36 - Phone Visit - C2 ☐ V105 - Day 43 - C2 ☐ V106 - Day 1B - C2 ☐ V107 - Day 8B - Phone Visit - C2 ☐ V108 - Day 15B - C2 ☐ V109 - Day 29B - C2 ☐ V110 - Day 91B - C2 ☐ V111 - Day 181B - C2 ☐ V112 - Day 366B - C2 ☐ Interim Visit ☐
Other	☐
If "Other", specify	_____

Form: Interim Visit Summary

What study procedures were completed at this visit? Select all that apply.	
Contraception	☐
Physical Exam	☐
Vital Signs	☐
Vital Signs - Post Vacc	☐
Pregnancy Test Results	☐
Specimen Collection - Blood	☐
Specimen Collection - NP/Nasal Swab	☐
SARS-CoV-2 Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Vaccination - Follow Up	☐
Booster	☐

Form: Follow-up Visit Summary

Did the participant complete this visit (or required visit procedures)?	Yes, visit completed ☐ No, visit missed ☐

If "No, visit missed", please complete the "Missed Visit" form.

Visit date: _____

Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐

If "Yes", complete the Study Termination CRF.

Were any new medical conditions/events (including hospitalizations or prolongation of existing hospitalizations) reported at this visit? Include any conditions reported after reviewing with the participant any medical history, obstetric history, and history of respiratory illnesses.	Yes ☐ No ☐

If "Yes", update the Medical History Log CRF.

Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐

If "Yes", update the Adverse Event Log.

Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐

If "Yes", update the Concomitant Medications Log.

Were any protocol deviations reported at this visit?	Yes ☐ No ☐

If "Yes", update the Protocol Deviations Log.

Were any additional study procedures or forms completed at this visit?	Yes ☐ No ☐

If "Yes", complete the Additional Study Procedures CRF.

Form: Demographics

Date of birth	
Age	Fixed Unit: yrs
Sex assigned at birth	Male ☐ Female ☐ Intersex ☐ Decline to answer ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☐ Prefer not to answer ☐ Unknown ☐

Race

Mark all that apply.

American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
White	☐
Other	☐
If "Other", specify (max. 200 characters):	

Form: Informed Consent

Informed consent date	_____
Was consent provided for specimen storage/use in secondary research?	Yes ☐ No ☐

Form: Contraception - Screening

Was the contraception assessment performed?	Yes ☐
	No ☐
If no, why?	Not of reproductive potential ☐
	Participant pregnant ☐
	Other ☐
If Other, specify:	_____

What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

Abstinence	☐
Oral Contraceptive pill	☐
Intrauterine Device (IUD)	☐
Injectable	☐
Contraceptive Patch	☐
Contraceptive Vaginal Ring	☐
Implant	☐
Other Contraceptive	☐
If "Other", specify	_____
Sterilization (tubal ligation, bilateral oophorectomy, bilateral salpingectomy, hysterectomy, or successful essure)	☐

Select Concomitant Medication Log line.

Select from the drop-down list 1	_____
Select from the drop-down list 2	_____

Form: Vital Signs Screening

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Time of assessment	
Height	Fixed Unit: cm
Weight	Fixed Unit: kg
BMI calculated	
Body temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min

Form: Inclusion Exclusion Criteria

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status If "Eligible and enrolled" end of form.	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐ Ineligible/Enrolled ☐
Date participant was found "Eligible/Not Enrolled", "Ineligible", or "Incomplete Screening".	_____
Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible".	I1. Individuals ≥ 18 years of age at the time of consent. ☐ I2. Received and completed COVID-19 vaccine under EUA dosing guidelines at least 12 weeks and no more than 20 weeks prior to enrollment (Cohort 1 only). ☐ I3. Willing and able to comply with all scheduled visits, vaccination plan, laboratory tests and other study procedures. ☐ I4. Determined by medical history, targeted physician examination and clinical judgement of the investigator to be in good health. ☐ I5. Female participants of childbearing potential may be enrolled in the study, given continuation of adequate contraception, negative pregnancy test and not currently breastfeeding. ☐ E1. Known history of SARS-CoV-2 infection. ☐ E2. Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or SARS-CoV-2 monoclonal antibody in preceding 90 days or simultaneous participation in another interventional study. ☐ E3. Receipt of SARS CoV-2 vaccine prior to study entry (Cohort 2 only). ☐ E4. A history of anaphylaxis, urticaria, or other significant adverse reaction requiring medical intervention after receipt of a vaccine or nanolipid particles. ☐ E5. Receipt of any investigational study product within 28 days prior to enrollment. ☐

Form: Inclusion Exclusion Criteria

	E6. Receipt of vaccine within 28 days prior to first dose (Day 1) or plans to receive a non-study vaccine within 28 days prior to or after any dose of study vaccine (with exception for seasonal influenza vaccine within 14 days). ☐
	E7. Bleeding disorder diagnosed by a doctor (e.g., factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with intramuscular injections or blood draws. ☐
	E8. Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition. ☐
	E9. Received systemic immunosuppressants or immune-modifying drugs for >14 days within 6 months prior to Screening (corticosteroids ≥ 20 mg/day). Topical tacrolimus allowed if not used within 14 days prior to Day 1. ☐
	E10. Received immunoglobulin, blood-derived products, within 90 days prior to first study vaccination. ☐
	E11. An immediate family member or household member of this study's personnel. ☐
	E12. Is acutely ill or febrile 72 hours prior to or at vaccine dosing (fever defined as ≥ 38.0°C/100.4°F). ☐
	E13. Investigator decision, specify ☐
If "Investigator decision", specify (max. 200 characters):	_____

Form: Enrollment

Enrollment date	_____
Was this participant enrolled into Cohort 1 or Cohort 2?	Cohort 1 ☐ Cohort 2 ☐
If Cohort 1, Select Group	1E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273 booster ☐ 2E: Previously dosed Moderna – mRNA-1273; Moderna – mRNA-1273 booster ☐ 3E: Previously dosed Pfizer/BioNTech – BNT162b2; Moderna – mRNA-1273 booster ☐ 4E: Previously dosed Janssen – Ad26.COV2-S; Janssen – Ad26.COV2-S booster ☐ 5E: Previously dosed Moderna – mRNA-1273; Janssen – Ad26.COV2-S booster ☐ 6E: Previously dosed Pfizer/BioNTech – BNT162b2; Janssen – Ad26.COV2-S booster ☐ 7E: Previously dosed Janssen – Ad26.COV2-S; Pfizer/BioNTech – BNT162b2 booster ☐ 8E: Previously dosed Moderna – mRNA-1273; Pfizer/BioNTech – BNT162b2 booster ☐ 9E: Previously dosed Pfizer/BioNTech – mRNA-BNT162b2; Pfizer/BioNTech – BNT162b2 booster ☐ 10E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273.211 booster ☐ 11E: Previously dosed Pfizer/BioNTech – BNT162b2; Moderna – mRNA-1273.211 booster ☐ 12E: Previously dosed Janssen – Ad26.COV2-S; Moderna – mRNA-1273 50 mcg dose booster ☐ 13E: Previously dosed Moderna – mRNA-1273; Moderna – mRNA-1273 50 mcg dose booster ☐ 14E: Previously dosed Pfizer/BioNTech –BNT162b2; Moderna – mRNA-1273 50 mcg dose booster ☐ 15E: Previously dosed Janssen – Ad26.COV2-S; Novavax – NVX-CoV2373 booster ☐ 16E: Previously dosed Moderna – mRNA-1273; Novavax – NVX-CoV2373 booster ☐

Form: Enrollment

	17E: Previously dosed Pfizer/BioNTech –BNT162b2; Novavax – NVX-CoV2373 booster ☐
If this participant is enrolling in Cohort 1, group "15E: Previously dosed Janssen – Ad26.COV2-S; Novavax – NVX-CoV2373 booster", was this participant previously enrolled in Cohort 1, Group "4E: Previously dosed Janssen – Ad26.COV2-S; Janssen – Ad26.COV2-S booster"?	Yes ☐ No ☐
If this participant is enrolling in Cohort 1, group "15E: Previously dosed Janssen – Ad26.COV2-S; Novavax – NVX-CoV2373 booster", was this participant previously enrolled in Cohort 1, Group "4E: Previously dosed Janssen – Ad26.COV2-S; Janssen – Ad26.COV2-S booster"?	Yes ☐ No ☐
If yes, provide this participant's PTID for group 4E	_____
TSDV1 Hidden Variable	_____
TSDV2 Hidden Variable	_____

Form: SARS-CoV-2 Vaccination

How was vaccination information obtained?	Vaccination card ☐ Medical records ☐ Participant report ☐ Other ☐
If "Other", specify	_____
Vaccine manufacturer	Pfizer/BioNTech – BNT162b2 ☐ Moderna – mRNA-1273 ☐ Janssen – Ad26.COV2-S ☐ Other ☐
If "Other", specify	_____
Date of first vaccination	_____
Date of second vaccination, if applicable	_____

Form: Vaccination - Enrollment

Date of vaccination	_____
Time of injection	_____
Location of injection	Right deltoid ☐
	Left deltoid ☐
Dose	First ☐
	Second ☐
Vaccine manufacturer	Moderna-mRNA-1273 ☐
	Other ☐
If "Other", specify	_____
Were there any study product administration errors?	Yes ☐
	No ☐
If "Yes", complete Study Product Administration Error form.	
Comments (max. 450 characters):	_____

Form: Vaccination - Follow Up

Was a vaccination administered at this visit?	Yes ☐
	No ☐
If No, specify reason not done	_____
Date of vaccination	_____
Time of injection	_____
Location of injection	Right deltoid ☐
	Left deltoid ☐
Dose	First ☐
	Second ☐
Vaccine manufacturer	Moderna-mRNA-1273 ☐
	Other ☐
If "Other", specify	_____
Were there any study product administration errors?	Yes ☐
	No ☐
If "Yes", complete Study Product Administration Error form.	
Comments (max. 450 characters):	_____

Form: Booster

Was a booster administered at this visit?	Yes ☐
	No ☐
If No, specify reason not done	_____
Date of booster	_____
Time of injection	_____
Location of injection	Right deltoid ☐
	Left deltoid ☐
Product manufacturer	Moderna-mRNA-1273 ☐
	Janssen – Ad26.COV2.S ☐
	Pfizer/BioNTech – BNT162b2 ☐
	Moderna – mRNA-1273.211 ☐
	Moderna – mRNA-1273 50 mcg dose ☐
	Novavax – NVX-CoV2373 ☐
	Other ☐
If "Other", specify	_____
Were there any study product administration errors?	Yes ☐
	No ☐
If "Yes", complete Study Product Administration Error form.	
Comments (max. 450 characters):	_____

Form: Physical Exam

Was a physical exam performed?	Yes ☐
	No ☐
Date of exam	_____
BODY SYSTEM	
HEENT	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Neck	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Musculoskeletal	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Lymph Nodes	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Heart/Cardiovascular	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Pulmonary/chest	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Abdomen	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Extremities	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Neurological	Not done ☐
	Normal ☐

Form: Physical Exam

	Abnormal ☐
If "Abnormal", specify:	_____
Skin	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
General appearance	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Other system finding	Not done ☐
	Normal ☐
	Abnormal ☐
If "Other system", specify system:	_____
If "Abnormal", specify:	_____
Comments (max. 200 characters):	_____

Form: Vital Signs

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Body temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min

Form: Vital Signs - Post Vacc

Were vital signs done post vaccination?	Yes ☐ No ☐
Date of assessment	
Body temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min

Form: Contraception

Was the contraception assessment performed?	Yes ☐ No ☐
If no, why?	Not of reproductive potential ☐ Participant pregnant ☐ Other ☐
If Other, specify:	_____
Visit	V1 - Screening/Enrollment - C1/C2 ☐ V2 - Day 8 - Phone Visit - C1 ☐ V3 - Day 15 - C1 ☐ V4 - Day 29 - C1 ☐ V5 - Day 91 - C1 ☐ V6 - Day 181 - C1 ☐ V7 - Day 366 - C1 ☐ V102 - Day 8 - Phone Visit - C2 ☐ V103 - Day 29 - C2 ☐ V104 - Day 36 - Phone Visit - C2 ☐ V105 - Day 43 - C2 ☐ V106 - Day 1B - C2 ☐ V107 - Day 8B - Phone Visit - C2 ☐ V108 - Day 15B - C2 ☐ V109 - Day 29B - C2 ☐ V110 - Day 91B - C2 ☐ V111 - Day 181B - C2 ☐ V112 - Day 366B - C2 ☐ Interim Visit ☐
If 'Interim visit', provide interim visit code	_____
Have there been any changes to your method(s) of birth control since the last visit?	Yes ☐ No ☐ Not applicable ☐

If YES, please complete all sections below that apply. If NO, end form.

Please select the Concomitant Medications that are current but have had updates.

Select Concomitant Medication Log line.	
Select from the drop-down list 1	_____
Select from the drop-down list 2	_____

Form: Contraception

Have you had a tubal ligation, bilateral oophorectomy, bilateral salpingectomy, hysterectomy, successful essure, or has your partner been vasectomized since last visit?	Yes ☐ No ☐
If yes, Date of procedure	_____
Have you started practicing abstinence, started a new oral contraceptive, an intrauterine device also called IUD, received an injection, started a contraceptive patch, had a contraceptive vaginal ring inserted, had a new implant or inserted, or started any other contraceptive since last visit?	Yes ☐ No ☐

If yes (with the exception of abstinence), please update Concomitant Medications and select the medication(s) below.

NOTE New medications are not required to be collected/entered on this form after Visit 4 for Cohort 1 and Visit 109 for Cohort 2.

If yes, select from the drop-down list 1	_____
If yes, select from the drop-down list 2	_____
Have you stopped practicing abstinence, stopped use of an oral contraceptive, stopped using an intrauterine device (also called IUD), stopped receiving injections, stopped using a contraceptive patch, had a contraceptive vaginal ring or implant removed or stopped any other contraceptive since last visit?	Yes ☐ No ☐

If yes (with the exception of abstinence), please update Concomitant Medications and select the medication(s) below.

If yes, select from the drop-down list 1	_____
If yes, select from the drop-down list 2	_____

Form: Pregnancy Test Results

Was a urine pregnancy test performed?	Yes ☐
	No ☐
If no, specify reason not done:	Not of reproductive potential ☐
	Participant pregnant ☐
	Other ☐
If Other, specify:	_____
Specimen date	_____
Collection time	_____
Pregnancy test result	Positive ☐
	Negative ☐
	Indeterminant ☐

If "Positive" at study product administration visit, do not administer study product. Complete Pregnancy Report and Pregnancy History forms, if applicable.

Comments (max. 450 characters): _____

Form: Specimen Collection - Blood

Specimen type	Whole blood for PBMC and plasma ☐ Serum ☐
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Is this specimen being collected for secondary research?	Yes ☐ No ☐

Specimen type	Whole blood for PBMC and plasma ☐ Serum ☐
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Is this specimen being collected for secondary research?	Yes ☐ No ☐

Form: Additional Study Procedures

Select any additional forms completed at this visit.	
Contraception	☐
Physical Exam	☐
Vital Signs	☐
Vital Signs - Post Vacc	☐
Pregnancy Test Results	☐
Specimen Collection - Blood	☐
Specimen Collection - NP/Nasal Swab	☐
SARS-CoV-2 Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Vaccination - Follow Up	☐
Booster	☐
Missed Study Product Administration	☐

Form: Reactogenicity - Baseline and Early

Was assessment done?	Yes ☐
If "No", specify reason not done below and end of form.	No ☐
Reason not done (max. 200 characters)	
Assessment time point	Baseline ■
	Early assessment ☐
Date of assessment	
Time of assessment	
Body temperature	Fixed Unit: C
If body temperature >= 38.0 C at baseline, DO NOT administer study product.	
Severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
SYSTEMIC SYMPTOMS	Not assessed ☐
If ANY symptoms are moderate or above: a) at baseline, do not administer study product or b) at early assessment, participant is to be seen by clinician within 48 hours unless symptoms are improving or resolved.	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
Chills	Potentially life-threatening ☐
Adverse event	
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐

Form: Reactogenicity - Baseline and Early

Adverse event	
Arthralgia/joint pain	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Headache	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Nausea	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
LOCAL SYMPTOMS	Vaccination 1 ☐ Vaccination 2 ☐ Booster ☐
Injection number	
Location of local assessment	Right deltoid ☐ Left deltoid ☐
Pain and/or tenderness If pain and/or tenderness symptoms are moderate or above at baseline, DO NOT administer study product.	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Is a vaccine-related lesion visible?	Yes ☐ No ☐
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm

Form: Reactogenicity - Baseline and Early

Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done? If "No", specify reason not done below and end of form.	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Assessment time point	Baseline ☐ Early assessment ■
Date of assessment	
Time of assessment	
Body temperature If body temperature >= 38.0 C at baseline, DO NOT administer study product.	Fixed Unit: C
Severity grade	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	

Form: Reactogenicity - Baseline and Early

SYSTEMIC SYMPTOMS

If ANY symptoms are moderate or above: a) at baseline, do not administer study product or b) at early assessment, participant is to be seen by clinician within 48 hours unless symptoms are improving or resolved.

Chills

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Malaise and/or fatigue

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Myalgia/body aches

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Arthralgia/joint pain

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Headache

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Nausea

- Not assessed ☐
- None ☐
- Mild ☐

Form: Reactogenicity - Baseline and Early

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Pain and/or tenderness If pain and/or tenderness symptoms are moderate or above at baseline, DO NOT administer study product.	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Is a vaccine-related lesion visible?	Yes ☐ No ☐
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm _____
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm _____
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐

Form: Reactogenicity - Baseline and Early

	Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	

Form: Reactogenicity - Daily Log

Complete the Daily Assessment Log through day 8. If symptoms continue past Day 8, record the resolution date on the Reactogenicity - Resolution of Symptoms form.

COMPLETE AT DAY 8 ONLY:

Are there any symptoms at a higher severity grade than baseline continuing at the end of Day 8 assessment?

If "Yes", complete the Reactogenicity - Resolution of Symptoms form.

- Yes ☐
- No ☐

Was assessment done?

If "No", specify reason not done below and end of form.

- Yes ☐
- No ☐

Reason not done (max. 200 characters) _____

Assessment time point

- Day 1 ■
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐

Date of assessment _____

Body temperature _____ Fixed Unit: C

Severity grade

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

SYSTEMIC SYMPTOMS

Chills

- Not assessed ☐
- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Potentially life-threatening ☐

Adverse event _____

Malaise and/or fatigue

- Not assessed ☐
- None ☐
- Mild ☐

Form: Reactogenicity - Daily Log

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐

Form: Reactogenicity - Daily Log

Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Comments (max. 450 characters):	_____
Was assessment done?	Yes ☐
If "No", specify reason not done below and end of form.	No ☐
Reason not done (max. 200 characters)	_____
Assessment time point	Day 1 ☐
	Day 2 ■
	Day 3 ☐
	Day 4 ☐

Form: Reactogenicity - Daily Log

	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	Day 8 ☐
Date of assessment	_____
Body temperature	Fixed Unit: C
	_____
Severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
SYSTEMIC SYMPTOMS	Not assessed ☐
	None ☐
Chills	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐

Form: Reactogenicity - Daily Log

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐

Form: Reactogenicity - Daily Log

	Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done? If "No", specify reason not done below and end of form.	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ■ Day 4 ☐ Day 5 ☐ Day 6 ☐ Day 7 ☐ Day 8 ☐
Date of assessment	
Body temperature	Fixed Unit: C
Severity grade	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	

Form: Reactogenicity - Daily Log

SYSTEMIC SYMPTOMS	Not assessed ☐
	None ☐
Chills	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐

Form: Reactogenicity - Daily Log

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐

Form: Reactogenicity - Daily Log

	Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done?	Yes ☐
If "No", specify reason not done below and end of form.	No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐
	Day 2 ☐
	Day 3 ☐
	Day 4 ■
	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	Day 8 ☐
Date of assessment	
Body temperature	Fixed Unit: C
Severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
SYSTEMIC SYMPTOMS	Not assessed ☐
	None ☐
Chills	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	

Form: Reactogenicity - Daily Log

Myalgia/body aches	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐ Vaccination 2 ☐ Booster ☐
Injection number	
Location of local assessment	Right deltoid ☐ Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐ No ☐
Pain and/or tenderness	Not assessed ☐ None ☐

Form: Reactogenicity - Daily Log

	Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done? If "No", specify reason not done below and end of form.	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐ Day 4 ☐ Day 5 ■ Day 6 ☐ Day 7 ☐ Day 8 ☐

Form: Reactogenicity - Daily Log

Date of assessment	
Body temperature	Fixed Unit: C
Severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
SYSTEMIC SYMPTOMS	Not assessed ☐
	None ☐
Chills	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	

Form: Reactogenicity - Daily Log

Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐

Form: Reactogenicity - Daily Log

Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done? If "No", specify reason not done below and end of form.	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐ Day 4 ☐ Day 5 ☐ Day 6 ■ Day 7 ☐ Day 8 ☐
Date of assessment	
Body temperature	Fixed Unit: C
Severity grade	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
SYSTEMIC SYMPTOMS Chills	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐

Form: Reactogenicity - Daily Log

	Potentially life-threatening ☐
Adverse event	_____
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____

Form: Reactogenicity - Daily Log

LOCAL SYMPTOMS	
Injection number	Vaccination 1 ☐ Vaccination 2 ☐ Booster ☐
Location of local assessment	Right deltoid ☐ Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐ No ☐
Pain and/or tenderness	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm _____
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm _____
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Comments (max. 450 characters):	_____

Form: Reactogenicity - Daily Log

Was assessment done?	Yes ☐
If "No", specify reason not done below and end of form.	No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ■
	Day 8 ☐
Date of assessment	
Body temperature	Fixed Unit: C
Severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
SYSTEMIC SYMPTOMS	Not assessed ☐
	None ☐
Chills	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Malaise and/or fatigue	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	
Myalgia/body aches	Not assessed ☐
	None ☐
	Mild ☐

Form: Reactogenicity - Daily Log

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

Form: Reactogenicity - Daily Log

	Potentially life-threatening ☐
Adverse event	
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	
Comments (max. 450 characters):	
Was assessment done? If "No", specify reason not done below and end of form.	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐ Day 4 ☐ Day 5 ☐ Day 6 ☐ Day 7 ☐ Day 8 ■
Date of assessment	
Body temperature	Fixed Unit: C

Form: Reactogenicity - Daily Log

Severity grade	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
SYSTEMIC SYMPTOMS	Not assessed ☐ None ☐
Chills	Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Malaise and/or fatigue	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Myalgia/body aches	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Arthralgia/joint pain	Not assessed ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Adverse event	_____
Headache	Not assessed ☐ None ☐ Mild ☐

Form: Reactogenicity - Daily Log

	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
LOCAL SYMPTOMS	Vaccination 1 ☐
	Vaccination 2 ☐
Injection number	Booster ☐
Location of local assessment	Right deltoid ☐
	Left deltoid ☐
Is a vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____
Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
	_____

Form: Reactogenicity - Daily Log

Severity grade	Not assessed ☐
	None ☐
	Not gradable ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Adverse event	_____
Comments (max. 450 characters):	_____

Form: Reactogenicity - Resolution of Symptoms

If no signs or symptoms are continuing at 11:59 p.m. Day 8, do not complete the resolution form. If the participant has any grade 3 symptoms at any point during the reactogenicity period or for any symptoms that are at a higher severity grade than baseline and were reported as continuing at 11:59 p.m. Day 8, report (1) the maximum severity grade experienced since 11:59 p.m. Day 8, and (2) the resolution date or the date the symptom returned to baseline severity grade. Mark "Not assessed" for all other signs and symptoms.

Maximum body temperature _____

Severity grade
- ☐ Not assessed
- ☐ None
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Potentially life-threatening

Resolution date _____

Adverse event _____

☐ Maximum body temperature not applicable

SYSTEMIC SIGNS AND SYMPTOMS

Chills
- ☐ Not assessed
- ☐ None
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Potentially life-threatening

Resolution date _____

Adverse event _____

Malaise and/or fatigue
- ☐ Not assessed
- ☐ None
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Potentially life-threatening

Resolution date _____

Adverse event _____

Myalgia/body aches
- ☐ Not assessed
- ☐ None
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Potentially life-threatening

Resolution date _____

Adverse event _____

Form: Reactogenicity - Resolution of Symptoms

Arthralgia/joint pain	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Resolution date	_____
Adverse event	_____
Headache	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Resolution date	_____
Adverse event	_____
Nausea	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐
Resolution date	_____
Adverse event	_____
LOCAL SYMPTOMS	
Location of injection	Right deltoid ☐
	Left deltoid ☐
Injection number	Vaccination 1 ☐
	Vaccination 2 ☐
	Booster ☐
Is vaccine-related lesion visible?	Yes ☐
	No ☐
Pain and/or tenderness severity grade	Not assessed ☐
	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Potentially life-threatening ☐

Form: Reactogenicity - Resolution of Symptoms

Resolution date	
Adverse event	
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Resolution date	
Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm
Severity grade	Not assessed ☐ None ☐ Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially life-threatening ☐
Resolution date	
Adverse event	
Comments (max. 450 characters):	

Form: Missed Visit

Target visit date	
Reason visit was missed	Unable to contact participant ☐ Unable to schedule visit within window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to healthcare facility ☐ Participant withdrew from study ☐ Participant deceased ☐ Other ☐
If "Other", specify:	
Steps taken to address the missed visit (corrective action plan)	

Form: Missed Study Product Administration

Visit date of missed study product administration	_____
What is the primary reason for missing the study product administration at this visit?	Pregnancy ☐ Participant unable to schedule visit within window ☐ Unable to contact participant ☐ Participant incarcerated ☐ Adverse event ☐ Reactogenicity event ☐ Participant refused vaccination ☐ Other ☐
If "Pregnancy", complete Pregnancy Report and Pregnancy History forms. If "Adverse event", complete Adverse Event log if condition meets AE reporting requirements as specified in the protocol.	
If "Other", specify:	_____
If "Adverse event", select AE.	_____
If "Reactogenicity event", specify:	_____

If "Adverse event" or "Reactogenicity event", indicate who made the decision to not administer study product.

Mark all that apply.

Clinician	☐
Participant	☐
PSRT	☐
Other	☐
Other, Specify	_____
Comments (max. 200 characters):	_____

Form: Study Product Administration Error

Date of visit when study product administration error(s) occurred _____

Describe the administration error(s).

Mark all that apply.

- Incorrect administration site ☐
  - Specify site: _____
- Incorrect product administered ☐
  - Specify product: _____
- Incorrect dose administered ☐
- Administered beyond product viability ☐
- Administered outside protocol-specified visit window ☐
- Other ☐
  - If "Other", specify (max. 200 characters): _____

OUTCOME

What action was taken as a result of study product administration error(s) described above?

- Discontinued future study product administration ☐
- No action taken ☐
- Other ☐

If "Discontinued future study product administration", complete Discontinuation of Study Product form.

If "Other", specify (max. 200 characters): _____

Form: Specimen Collection - NP/Nasal Swab

Was specimen collected?	Yes ☐ No ☐
If "No", provide reason and end of form. Primary reason specimen was not collected	Participant declined ☐ Participant unable to provide sample ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
Specimen collection date	_____
Specimen collection time	_____
Was the procedure performed by participant or by staff?	Participant ☐ Staff ☐
Swab type	Nasopharyngeal ☐ Nasal ☐
Comments (max. 600 characters):	_____

Form: SARS-CoV-2 Test Results

Specimen collection date	_____
Test result	Positive ☐
	Negative ☐
	Indeterminate ☐
Test type	Molecular ☐
	Antigen ☐
	Unknown ☐

Form: Medical History Y/N

Does the participant have any medical history to report?	Yes ☐
	No ☐

If "Yes", update the Medical History log.

Form: Medical History

Log Page #: _____

Date medical condition/event reported	
Description of medical history condition/event	
Start date of medical history condition/event	
Is the condition ongoing?	Yes ☐ No ☐
Date medical history/condition ended/resolved	
Comments (max. 200 characters):	

Form: Concomitant Medications Y/N

Were any concomitant medications taken?	Yes ☐
	No ☐

If "Yes", update the Concomitant Medications log.

Form: Concomitant Medications Log Page #: _____

Medication name _____

If the medication entered is a booster received outside of the study or protocol, check this box and enter "SARS-CoV-2 Booster: [Manufacturer]" under "Indication" below. ☐

If box is checked, please also complete a Protocol Deviation.

Indication _____

Date started _____

Date stopped

Or _____

Ongoing ☐

Dose _____

Dose units

- Gram ☐
- Microgram ☐
- Milligram ☐
- Milliliters ☐
- Capsules ☐
- Drops ☐
- Puffs ☐
- Sachets ☐
- Suppository ☐
- Tablets ☐
- Units ☐
- Unknown ☐
- Other ☐

If "Other", specify: _____

Frequency

- As needed ☐
- Daily ☐
- Twice per day ☐
- Three times per day ☐
- Four times per day ☐
- Monthly ☐
- Every hour ☐
- Every night at bedtime ☐
- Once ☐
- Other ☐

If "Other", specify: _____

Route

- Oral ☐
- Intramuscular ☐

Form: Concomitant Medications

	Intravenous ☐
	Topical ☐
	Inhalation ☐
	Vaginal ☐
	Rectal ☐
	Subcutaneous ☐
	Other ☐
If "Other", specify:	_____
Taken for a reported unsolicited AE or SAE as recorded in the AE log	Yes ☐
	No ☐
If "Yes", select adverse event.	_____

Form: Adverse Event Y/N

Has the participant experienced an adverse event during the study?	Yes ☐ No ☐

If "Yes", update the Adverse Event log.

Form: Adverse Event

Log Page #: _____

Date AE reported to site	_____
Adverse event (AE)	_____
Onset date	_____
Is this a solicited AE (reactogenicity)?	Yes ☐
	No ☐
At which visit was this adverse event first reported?	V1 - Screening/Enrollment - C1/C2 ☐
	V2 - Day 8 - Phone Visit - C1 ☐
	V3 - Day 15 - C1 ☐
	V4 - Day 29 - C1 ☐
	V5 - Day 91 - C1 ☐
	V6 - Day 181 - C1 ☐
	V7 - Day 366 - C1 ☐
	V102 - Day 8 - Phone Visit - C2 ☐
	V103 - Day 29 - C2 ☐
	V104 - Day 36 - Phone Visit - C2 ☐
	V105 - Day 43 - C2 ☐
	V106 - Day 1B - C2 ☐
	V107 - Day 8B - Phone Visit - C2 ☐
	V108 - Day 15B - C2 ☐
	V109 - Day 29B - C2 ☐
	V110 - Day 91B - C2 ☐
	V111 - Day 181B - C2 ☐
	V112 - Day 366B - C2 ☐
	Interim Visit ☐
If "Interim visit", specify interim visit code.	_____
Is the AE still ongoing?	Yes ☐
	No ☐
If "No", outcome date	_____
Severity grade	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Grade 5 (Death) ☐
Relationship to study product	Related ☐
	Not related ☐

Record pertinent details for relationship assessment in "Comments".

Form: Adverse Event

If "Not related", specify alternate etiology.

If etiology not known, enter "Unknown". _____

Action taken with study product

- Dose not changed ☐
- Dose reduced ☐
- Dose increased ☐
- Drug withdrawn ☐
- Drug interrupted ☐
- Not applicable ☐

Action taken ☐

Mark "None" or all that apply.

None

- Medication(s) ☐
- Therapeutic procedure/surgery ☐
- Diagnostic procedure ☐
- Other ☐

If "Other", specify (max. 200 characters): _____

Status/Outcome

- Recovered/Resolved ☐
- Recovering/Resolving ☐
- Recovered/Resolved with Sequelae ☐
- Not recovered/Not resolved ☐
- Fatal ☐
- Unknown ☐

Is this a serious adverse event (SAE) according to ICH/GCP or protocol guidelines?

- Yes ☐
- No ☐

If "Yes", check all that apply.

- Results in death ☐
- Is life-threatening ☐
- Requires inpatient hospitalization or prolongation of existing hospitalization ☐
- Results in persistent or significant disability/incapacity ☐
- Is a congenital anomaly/birth defect ☐
- Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above ☐

Form: Adverse Event

Does this AE meet criteria for an AE of Special Interest (AESI)?	Yes ☐ No ☐
SAE/AESI onset date	_____
Does this AE meet criteria for a Suspected Unexpected Serious Adverse Reaction (SUSAR)?	Yes ☐ No ☐
Does this AE meet criteria for a New-Onset Chronic Medical Condition (NOCMC)?	Yes ☐ No ☐
Does this AE meet criteria for a Medically Attended Adverse Event (MAAE)?	Yes ☐ No ☐
If MAAE, specify	_____
Does this AE meet criteria for an Unanticipated Problem (UP)?	Yes ☐ No ☐
Event to be evaluated for halting criteria?	Yes ☐ No ☐
According to the medical monitor, is this halting criteria?	Yes ☐ No ☐
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐
Comments (max. 450 characters):	_____

Form: Protocol Deviations Y/N

Have any protocol deviations been reported?	Yes ☐
	No ☐

If "Yes", update the Protocol Deviations log.

Form: Protocol Deviations Log Page #: _____

Site awareness date	_____
Deviation date	_____
Visit	V1 - Screening/Enrollment - C1/C2 ☐
	V2 - Day 8 - Phone Visit - C1 ☐
	V3 - Day 15 - C1 ☐
	V4 - Day 29 - C1 ☐
	V5 - Day 91 - C1 ☐
	V6 - Day 181 - C1 ☐
	V7 - Day 366 - C1 ☐
	V102 - Day 8 - Phone Visit - C2 ☐
	V103 - Day 29 - C2 ☐
	V104 - Day 36 - Phone Visit - C2 ☐
	V105 - Day 43 - C2 ☐
	V106 - Day 1B - C2 ☐
	V107 - Day 8B - Phone Visit - C2 ☐
	V108 - Day 15B - C2 ☐
	V109 - Day 29B - C2 ☐
	V110 - Day 91B - C2 ☐
	V111 - Day 181B - C2 ☐
	V112 - Day 366B - C2 ☐
	Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
OR if protocol deviation did not occur during a visit, check this box	☐
Has or will this deviation be reported to local IRB/EC?	Yes ☐
	No ☐
Type of deviation	Inappropriate enrollment ☐
	Failure to follow randomization or blinding procedures ☐
	Study product management deviation ☐
	Study product dispensing error ☐
	Study product use/non-use deviation ☐
	Conduct of non-protocol procedure ☐
	Improper AE/SAE ☐
	Unreported AE ☐
	Unreported SAE/AESI ☐
	Breach of confidentiality ☐
	Physical assessment deviation ☐

Form: Protocol Deviations

	Lab assessment deviation ☐
	Mishandled lab specimen ☐
	Staff performing duties that they are not qualified to perform ☐
	Use of non-IRB/EC-approved materials ☐
	Use of excluded concomitant mediations, devices, or non-study products ☐
	Informed consent process deviation ☐
	Visit completed outside of window ☐
	Too few aliquots obtained ☐
	Required procedure not conducted ☐
	Other ☐
Description of deviation	_____
Plans and/or action taken to address the deviation	_____
Plans and/or action taken to prevent future occurrences of the deviation	_____
Deviation reported by	_____

Form: Pregnancy Report

Date pregnancy reported to site	_____
Visit at which this pregnancy was reported	V1 - Screening/Enrollment - C1/C2 ☐ V2 - Day 8 - Phone Visit - C1 ☐ V3 - Day 15 - C1 ☐ V4 - Day 29 - C1 ☐ V5 - Day 91 - C1 ☐ V6 - Day 181 - C1 ☐ V7 - Day 366 - C1 ☐ V102 - Day 8 - Phone Visit - C2 ☐ V103 - Day 29 - C2 ☐ V104 - Day 36 - Phone Visit - C2 ☐ V105 - Day 43 - C2 ☐ V106 - Day 1B - C2 ☐ V107 - Day 8B - Phone Visit - C2 ☐ V108 - Day 15B - C2 ☐ V109 - Day 29B - C2 ☐ V110 - Day 91B - C2 ☐ V111 - Day 181B - C2 ☐ V112 - Day 366B - C2 ☐ Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
Date of onset of last menstrual period	_____
Or	
Amenorrheic for past 6 months	☐
Estimated date of delivery	_____
What primary information was used to estimate the date of delivery?	Last menstrual period ☐ Initial ultrasound <20 weeks ☐ Initial ultrasound >= 20 weeks ☐ Physical examination ☐ Conception date by assisted reproduction ☐ Other ☐
If delivery date was determined by ultrasound please provide date of ultrasound?	_____
If "Other", specify:	_____
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete Pregnancy History form.	

Form: Pregnancy History

Has the participant ever been pregnant before?	Yes ☐ No ☐
Do not include the current pregnancy	
If "No", end of form.	
Number of extremely preterm live births (<25 weeks)	_____
Number of very preterm live births (25 - 31 weeks)	_____
Number of early preterm live births (32 - 33 weeks)	_____
Number of late preterm live births (34 - 36 weeks)	_____
Number of early term live births (37 - 38 weeks)	_____
Number of full term live births (39 - 40 weeks)	_____
Number of late term live births (41 weeks)	_____
Number of post term live births (>= 42 weeks)	_____
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	_____
Number of spontaneous abortions (Less than 20 weeks)	_____
Number of therapeutic/elective abortions	_____
Number of ectopic pregnancies	_____
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____

Form: Pregnancy Outcome

Is the outcome of this pregnancy obtainable? If "No", end of form.	Yes ☐ No ☐
How many pregnancy outcomes resulted from this reported pregnancy?	_____
Outcome Date	_____
Place of delivery/outcome	Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other ☐
If "Other", specify:	_____
Specify outcome If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Method"	Full term live birth (greater than or equal to 37 weeks) ☐ Premature live birth (less than 37 weeks) ☐ Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks) ☐ Spontaneous abortion (less than 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐
If "Other", specify:	_____
If "Stillbirth/intrauterine fetal demise" was an autopsy done?	Yes ☐ No ☐
If "Yes" was the reason for the stillbirth/intrauterine fetal demise determined? Please explain.	_____
If spontaneous, therapeutic, or elective abortion What was the gestational age of the fetus in weeks?	_____
What was the gestational age of the fetus in days? OR	_____
Gestational age of fetus unavailable	☐
If spontaneous, therapeutic, or elective abortion Were there any abnormalities? If Yes, please explain.	_____
If the abortion was for therapeutic reasons, was it due to the mother or the fetus?	Mother ☐ Fetus ☐
Method	Cesarean delivery ☐

Form: Pregnancy Outcome

	Vaginal delivery - normal, unassisted ☐ Vaginal delivery - assisted (forceps, vacuum) ☐ Other ☐
Provide a brief narrative of the circumstances (max. 400 characters).	_____
Post pregnancy weight	Fixed Unit: kg _____
Date of post pregnancy weight	_____
Were there any complications related to the pregnancy outcome?	Yes ☐ No ☐

If the subject experienced any maternal complication during this pregnancy complete the Adverse Event form or SAE form even if the AE start date is outside of the AE reporting period for the study.

If "No", go to "Were any fetal/infant congenital anomalies identified?".

Delivery-related complications. Mark "None" or all that apply.	☐
None	
Intrapartum hemorrhage	☐
Postpartum hemorrhage	☐
Non-reassuring fetal status	☐
Chorioamnionitis	☐
Other	☐
If "Other", specify:	_____
Non-delivery related complications.Mark "None" or all that apply.	☐
None	
Hypertensive disorders of pregnancy	☐
Gestational diabetes	☐
Other	☐
If "Other", specify:	_____

Form: Pregnancy Outcome

Were any fetal/infant congenital anomalies identified? Mark all that apply. If "No" or "Unknown", go to "Complete the infant items below for live births only."	Yes ☐ No ☐ Not assessed ☐ Unknown ☐

If Yes, complete the Adverse Event form for a Serious Adverse Event even if it is outside the AE reporting period.

Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Musculoskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐
Chromosomal	☐
Cranio-facial (structural)	☐
Hematologic	☐
Infectious	☐
Endocrine/metabolic	☐
Other	☐
Describe congenital anomaly/defect (max. 200 characters).	_____
Has the infant been ill or hospitalized? (Does not include well-child visits)	Yes ☐ No ☐
If "Yes", specify	_____
Complete the infant items below for live births and stillbirths. Otherwise, end of form. Infant sex	Male ☐ Female ☐ Intersex ☐ Decline to answer ☐
Infant birth weight	Fixed Unit: kg

Or

	_____

Form: Pregnancy Outcome

Infant birth weight unavailable	☐
Infant birth length	Fixed Unit: cm
Or	
Infant birth length unavailable	☐
Infant birth head circumference	Fixed Unit: cm
Or	
Infant birth head circumference unavailable	☐
Infant birth abdominal circumference	Fixed Unit: cm
Or	
Infant birth abdominal circumference unavailable	☐
Infant gestational age by examination in weeks	Fixed Unit: Weeks
Infant gestational age by examination in days	Fixed Unit: Days
Or	
Infant gestational age by examination unavailable	☐
Size for gestational age	SGA ☐ AGA ☐ LGA ☐
1 minute Apgar score	
5 minute Apgar score	
Cord pH	

Form: Participant Transfer

Name of transferring study site	Atlanta - VTEU ☐ Atlanta – ECC VTEU ☐ Cincinnati - VTEU ☐ Galveston - UTMB VTEU ☐ Houston - VTEU ☐ Mineola ☐ New York - Bellevue ☐ Pittsburgh - Vanderbilt VTEU ☐ Rochester - VTEU ☐ Seattle - Kaiser VTEU ☐ Seattle - UW VTEU ☐ University of Maryland Baltimore VTEU ☐
Name of receiving study site	Atlanta - VTEU ☐ Atlanta – ECC VTEU ☐ Cincinnati - VTEU ☐ Galveston - UTMB VTEU ☐ Houston - VTEU ☐ Mineola ☐ New York - Bellevue ☐ Pittsburgh - Vanderbilt VTEU ☐ Rochester - VTEU ☐ Seattle - Kaiser VTEU ☐ Seattle - UW VTEU ☐ University of Maryland Baltimore VTEU ☐
Visit of last completed contact with participant	V1 - Screening/Enrollment - C1/C2 ☐ V2 - Day 8 - Phone Visit - C1 ☐ V3 - Day 15 - C1 ☐ V4 - Day 29 - C1 ☐ V5 - Day 91 - C1 ☐ V6 - Day 181 - C1 ☐ V7 - Day 366 - C1 ☐ V102 - Day 8 - Phone Visit - C2 ☐ V103 - Day 29 - C2 ☐ V104 - Day 36 - Phone Visit - C2 ☐ V105 - Day 43 - C2 ☐ V106 - Day 1B - C2 ☐ V107 - Day 8B - Phone Visit - C2 ☐

Form: Participant Transfer

	V108 - Day 15B - C2 ☐
	V109 - Day 29B - C2 ☐
	V110 - Day 91B - C2 ☐
	V111 - Day 181B - C2 ☐
	V112 - Day 366B - C2 ☐
	Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

Form: Participant Receipt

Name of receiving study site	Atlanta - VTEU ☐ Atlanta – ECC VTEU ☐ Cincinnati - VTEU ☐ Galveston - UTMB VTEU ☐ Houston - VTEU ☐ Mineola ☐ New York - Bellevue ☐ Pittsburgh - Vanderbilt VTEU ☐ Rochester - VTEU ☐ Seattle - Kaiser VTEU ☐ Seattle - UW VTEU ☐ University of Maryland Baltimore VTEU ☐
Name of transferring study site	Atlanta - VTEU ☐ Atlanta – ECC VTEU ☐ Cincinnati - VTEU ☐ Galveston - UTMB VTEU ☐ Houston - VTEU ☐ Mineola ☐ New York - Bellevue ☐ Pittsburgh - Vanderbilt VTEU ☐ Rochester - VTEU ☐ Seattle - Kaiser VTEU ☐ Seattle - UW VTEU ☐ University of Maryland Baltimore VTEU ☐
Date participant received at receiving site	_____

Form: Discontinuation of Study Product

Date of study product completion or discontinuation	_____
Primary reason for ending study product use	Scheduled exit visit/end of study ☐ Death ☐ Voluntary withdrawal by subject ☐ Investigator decision ☐ Lost to follow up ☐ Termination of site by sponsor ☐ Protocol deviation ☐ Adverse event (not including death) ☐ Pregnancy ☐ Study terminated by sponsor ☐ Participant unable to adhere to visit schedule ☐ Participant relocated, no follow-up planned ☐ Reactogenicity symptom ☐ Became inelligble after enrollment ☐ Confirmed SARS CoV-2 infection ☐ Receipt of SARS-CoV-2 vaccine outside of study ☐ Other, specify ☐
If "Other", specify (max. 200 characters):	_____
If “Adverse Event” or "Death" or “Confirmed SARS CoV-2 infection”, select applicable event.	_____

Form: Study Termination

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Voluntary withdrawal by subject ☐ Investigator decision ☐ Lost to follow-up ☐ Termination of site by sponsor ☐ Protocol deviation ☐ Adverse event (not including death) ☐ Pregnancy ☐ Study terminated by sponsor ☐ Participant unable to adhere to visit schedule ☐ Participant relocated, no follow-up planned ☐ Reactogenicity symptom ☐ Became ineligible after enrollment ☐ Confirmed SARS CoV-2 infection ☐ Cohort 1 group 4E Participant rolled over into Cohort 1 group 15E ☐ Other, specify ☐
If "Other" or "Became ineligible after enrollment", specify (max. 200 characters):	
If "Protocol Deviation", select applicable protocol deviation.	
If "Adverse event" or "Death" or "Confirmed SARS CoV-2 infection", select applicable adverse event.	
If "Death", enter date of death.	