

Participant ID: _____

IDCRC 21-00012

Visit Code: _____

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.COVID-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.COVID-S; Janssen –

Ad26.COVID-S booster

5E: Previously dosed Moderna –

mRNA-1273; Janssen –

Ad26.COVID-S booster

6E: Previously dosed

Pfizer/BioNTech – BNT162b2;

Janssen – Ad26.COVID-S booster

7E: Previously dosed Janssen –

Ad26.COVID-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.COVID-S; Moderna –

mRNA-1273.211 booster

11E: Previously dosed

Pfizer/BioNTech – BNT162b2;

Moderna – mRNA-1273.211

booster

12E: Previously dosed Janssen –

Ad26.COVID-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.COVID-S; Novavax –

NVX-CoV2373 booster

16E: Previously dosed Moderna

– mRNA-1273; Novavax –

NVX-CoV2373 booster

Participant ID: _____

IDCRC 21-00012

Visit Code: _____

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

V98 - Day 273 - 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

V113 - Day 1C - C2

V114 - Day 8C - Phone Visit - C2

Form: Interim Visit Summary

	V115- Day 15C - C2	<input type="checkbox"/>
	V116 - Day 29C - C2	<input type="checkbox"/>
	V117 - Day 91C - C2	<input type="checkbox"/>
	V118 - Day 181C - C2	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>
Other		<input type="checkbox"/>
If "Other", specify _____		
What study procedures were completed at this visit? Select all that apply.		
Contraception		<input type="checkbox"/>
Physical Exam		<input type="checkbox"/>
Vital Signs		<input type="checkbox"/>
Vital Signs - Post Vacc		<input type="checkbox"/>
Pregnancy Test Results		<input type="checkbox"/>
Specimen Collection - Blood		<input type="checkbox"/>
Specimen Collection - Mucosa		<input type="checkbox"/>
Specimen Collection - NP/Nasal Swab		<input type="checkbox"/>
SARS-CoV-2 Test Results		<input type="checkbox"/>
Participant Receipt		<input type="checkbox"/>
Participant Transfer		<input type="checkbox"/>
Vaccination - Follow Up		<input type="checkbox"/>
Booster		<input type="checkbox"/>

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? Yes
Include any conditions reported after reviewing with the participant any medical history, obstetric history, and history of respiratory illnesses. 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: Cohort 2 Extension

Did the participant meet all eligibility criteria to enter the Cohort 2 extension and sign the updated informed consent?

Yes

No

If No, enter reason below.

If Yes, skip to Date of Updated Informed Consent.

Reason not continuing in Cohort 2 extension (max. 200 characters): _____

Date of updated informed consent. _____

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): _____

Participant ID: _____

IDCRC 21-00012

Visit Code: _____

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 Eligible and enrolled

If "Eligible and enrolled" end of form.

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".

11. Individuals \geq 18 years of age at the time of consent.

12. Received and completed primary mRNA COVID-19 vaccine under EUA dosing guidelines and one or two doses of Ad26.COVS at least 12 weeks prior to enrollment (Cohort 1 only).

13. Willing and able to comply with all scheduled visits, vaccination plan, laboratory tests and other study procedures.

14. Determined by medical history, targeted physician examination and clinical judgement of the investigator to be in good health.

15. 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.

Form: Inclusion Exclusion Criteria

-
- E5. Receipt of any investigational study product within 28 days prior to enrollment.
 - 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 \geq 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 \geq 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.COVID-S; Moderna –
mRNA-1273 booster2E: Previously dosed Moderna – mRNA-1273; Moderna –
mRNA-1273 booster3E: Previously dosed Pfizer/BioNTech – BNT162b2;
Moderna – mRNA-1273 booster4E: Previously dosed Janssen – Ad26.COVID-S; Janssen –
Ad26.COVID-S booster5E: Previously dosed Moderna – mRNA-1273; Janssen –
Ad26.COVID-S booster6E: Previously dosed Pfizer/BioNTech – BNT162b2;
Janssen – Ad26.COVID-S booster7E: Previously dosed Janssen – Ad26.COVID-S; Pfizer/BioNTech –
BNT162b2 booster8E: Previously dosed Moderna – mRNA-1273; Pfizer/BioNTech –
BNT162b2 booster9E: Previously dosed Pfizer/BioNTech –
mRNA-BNT162b2;Pfizer/BioNTech – BNT162b2
booster10E: Previously dosed Janssen – Ad26.COVID-S; Moderna –
mRNA-1273.211 booster11E: Previously dosed Pfizer/BioNTech – BNT162b2;
Moderna – mRNA-1273.211

booster

12E: Previously dosed Janssen – Ad26.COVID-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.COVID-S; Novavax –
NVX-CoV2373 booster16E: 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.COVID-2-S; Novavax – NVX-CoV2373 booster", was this participant previously enrolled in Cohort 1, Group "4E: Previously dosed Janssen – Ad26.COVID-2-S; Janssen – Ad26.COVID-2-S booster"? Yes
No

If this participant is enrolling in Cohort 1, group "15E: Previously dosed Janssen – Ad26.COVID-2-S; Novavax – NVX-CoV2373 booster", was this participant previously enrolled in Cohort 1, Group "4E: Previously dosed Janssen – Ad26.COVID-2-S; Janssen – Ad26.COVID-2-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	<input type="checkbox"/>
	Medical records	<input type="checkbox"/>
	Participant report	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If "Other", specify	_____
Vaccine manufacturer	Pfizer/BioNTech - BNT162b2 <input type="checkbox"/>
	Moderna - mRNA-1273 <input type="checkbox"/>
	Janssen - Ad26.COV2-S <input type="checkbox"/>
	Other <input type="checkbox"/>

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.COVS.5
Pfizer/BioNTech - BNT162b2
Moderna - mRNA-1273.211
Moderna - mRNA-1273 50 mcg
dose
Novavax - NVX-CoV2373
Moderna - mRNA-1273.222
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

V98 - Day 273 - 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

V113 - Day 1C - C2

V114 - Day 8C - Phone Visit - C2

V115 - Day 15C - C2

V116 - Day 29C - C2

V117 - Day 91C - C2

V118 - Day 181C - 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

Form: Contraception

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

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: Specimen Collection - Mucosa

Specimen type Nasosorption swab
Oracol swab
Flocked swab

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was consent to use for secondary research withdrawn?

If Yes, check the box, otherwise leave blank.

Specimen type Nasosorption swab
Oracol swab
Flocked swab

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was consent to use for secondary research withdrawn?

If Yes, check the box, otherwise leave blank.

Specimen type Nasosorption swab
Oracol swab
Flocked swab

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was consent to use for secondary research withdrawn?

If Yes, check the box, otherwise leave blank.

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 - Mucosa

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 \geq 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 <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
Adverse event	
Headache	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
Adverse event	
Nausea	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
Adverse event	
LOCAL SYMPTOMS	Vaccination 1 <input type="radio"/>
	Vaccination 2 <input type="radio"/>
	Booster <input type="radio"/>
Injection number	
Location of local assessment	Right deltoid <input type="radio"/>
	Left deltoid <input type="radio"/>
Pain and/or tenderness	Not assessed <input type="radio"/>
If pain and/or tenderness symptoms are moderate or above at baseline, DO NOT administer study product.	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
Adverse event	
Is a vaccine-related lesion visible?	Yes <input type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event _____

Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".) _____ Fixed Unit: cm

Severity grade	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

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 Baseline

Early assessment

Date of assessment _____

Time of assessment _____

Body temperature _____ Fixed Unit: C

If body temperature \geq 38.0 C at baseline, DO NOT administer study product.

Severity grade	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event _____

Form: Reactogenicity - Baseline and Early

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

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

Booster

Injection number _____

Location of local assessment

Right deltoid

Left deltoid

Pain and/or tenderness

Not assessed

None

Mild

Moderate

Severe

Potentially life-threatening

If pain and/or tenderness symptoms are moderate or above at baseline, DO NOT administer study product.

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

Participant ID: _____

IDCRC 21-00012

Visit Code: _____

Form: Reactogenicity - Baseline and Early

_____	Potentially life-threatening <input type="checkbox"/>
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: Yes
No

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.

Was assessment done? Yes
No

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

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

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

Booster

Injection number _____

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
No

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

Reason not done (max. 200 characters) _____
Assessment time point Day 1
Day 2
Day 3
Day 4

Form: Reactogenicity - Daily Log

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

Form: Reactogenicity - Daily Log

	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

<u>Adverse event</u>	
Headache	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

<u>Adverse event</u>	
Nausea	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

<u>Adverse event</u>	
LOCAL SYMPTOMS	Vaccination 1 <input type="radio"/>
	Vaccination 2 <input type="radio"/>
	Booster <input type="radio"/>

<u>Injection number</u>	
Location of local assessment	Right deltoid <input type="radio"/>
	Left deltoid <input type="radio"/>
Is a vaccine-related lesion visible?	Yes <input type="radio"/>
	No <input type="radio"/>

Pain and/or tenderness	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

<u>Adverse event</u>	
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm

Severity grade	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>

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? _____ 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 _____

Form: Reactogenicity - Daily Log

SYSTEMIC SYMPTOMS	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
Chills	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event	_____
Malaise and/or fatigue	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event	_____
Myalgia/body aches	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event	_____
Arthralgia/joint pain	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event	_____
Headache	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event	_____
Nausea	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>

Form: Reactogenicity - Daily Log

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

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 <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event

Arthralgia/joint pain	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event

Headache	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event

Nausea	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Adverse event

LOCAL SYMPTOMS	Vaccination 1 <input type="radio"/>
	Vaccination 2 <input type="radio"/>
	Booster <input type="radio"/>

Injection number

Location of local assessment	Right deltoid <input type="radio"/>
	Left deltoid <input type="radio"/>

Is a vaccine-related lesion visible?	Yes <input type="radio"/>
	No <input type="radio"/>

Pain and/or tenderness	Not assessed <input type="radio"/>
	None <input type="radio"/>

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? _____ Yes

_____ No

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

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	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event

Nausea	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event

LOCAL SYMPTOMS	Vaccination 1	<input type="radio"/>
	Vaccination 2	<input type="radio"/>
	Booster	<input type="radio"/>

Injection number		
Location of local assessment	Right deltoid	<input type="radio"/>
	Left deltoid	<input type="radio"/>

Is a vaccine-related lesion visible?	Yes	<input type="radio"/>
	No	<input type="radio"/>

Pain and/or tenderness	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event

Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm	
---	----------------	--

Severity grade	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Not gradable	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

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

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	Vaccination 1	<input type="checkbox"/>
	Vaccination 2	<input type="checkbox"/>
	Booster	<input type="checkbox"/>

Injection number	
Location of local assessment	Right deltoid <input type="checkbox"/>
	Left deltoid <input type="checkbox"/>

Is a vaccine-related lesion visible?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Pain and/or tenderness	Not assessed <input type="checkbox"/>
	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Potentially life-threatening <input type="checkbox"/>

Adverse event	
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm

Severity grade	Not assessed <input type="checkbox"/>
	None <input type="checkbox"/>
	Not gradable <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Potentially life-threatening <input type="checkbox"/>

Adverse event	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm

Severity grade	Not assessed <input type="checkbox"/>
	None <input type="checkbox"/>
	Not gradable <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Potentially life-threatening <input type="checkbox"/>

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

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? 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

Form: Reactogenicity - Daily Log

Severity grade	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event		
SYSTEMIC SYMPTOMS	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
Chills	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event		
Malaise and/or fatigue	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event		
Myalgia/body aches	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event		
Arthralgia/joint pain	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

Adverse event		
Headache	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>

Form: Reactogenicity - Daily Log

	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

<hr/> Adverse event <hr/>		
Nausea	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

<hr/> Adverse event <hr/>		
LOCAL SYMPTOMS	Vaccination 1	<input type="radio"/>
	Vaccination 2	<input type="radio"/>
	Booster	<input type="radio"/>

<hr/> Injection number <hr/>		
Location of local assessment	Right deltoid	<input type="radio"/>
	Left deltoid	<input type="radio"/>

<hr/> Is a vaccine-related lesion visible? <hr/>		
	Yes	<input type="radio"/>
	No	<input type="radio"/>

<hr/> Pain and/or tenderness <hr/>		
	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

<hr/> Adverse event <hr/>		
Erythema/redness largest diameter (Record in "xx.x", and if none record "0.0".)	Fixed Unit: cm	

<hr/> Severity grade <hr/>		
	Not assessed	<input type="radio"/>
	None	<input type="radio"/>
	Not gradable	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Potentially life-threatening	<input type="radio"/>

<hr/> Adverse event <hr/>		
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 <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

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 <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Resolution date _____

Adverse event _____

Headache	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Resolution date _____

Adverse event _____

Nausea	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

Resolution date _____

Adverse event _____

LOCAL SYMPTOMS

Location of injection	Right deltoid <input type="radio"/>
	Left deltoid <input type="radio"/>

Injection number	Vaccination 1 <input type="radio"/>
	Vaccination 2 <input type="radio"/>
	Booster <input type="radio"/>

Is vaccine-related lesion visible?	Yes <input type="radio"/>
	No <input type="radio"/>

Pain and/or tenderness severity grade	Not assessed <input type="radio"/>
	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>

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 <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
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 <input type="radio"/>
	None <input type="radio"/>
	Not gradable <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Potentially life-threatening <input type="radio"/>
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.

Participant declined

Participant unable to provide sample

Primary reason specimen was not collected

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

Date medical condition/event reported	_____
Description of medical history condition/event	_____
Start date of medical history condition/event	_____
Is the condition ongoing?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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

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	<input type="checkbox"/>
	Topical	<input type="checkbox"/>
	Inhalation	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If "Other", specify: _____

Taken for a reported unsolicited AE or SAE as recorded in the AE log	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "Yes", select adverse event. _____

Participant ID: _____

IDCRC 21-00012

Visit Code: _____

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

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
V98 - Day 273 - 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
V113 - Day 1C - C2
V114 - Day 8C - Phone Visit - C2
V115 - Day 15C - C2
V116 - Day 29C - C2
V117 - Day 91C - C2
V118 - Day 181C - 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)

Form: Adverse Event

	Grade 4 (Potentially life-threatening) <input type="checkbox"/>
	Grade 5 (Death) <input type="checkbox"/>

Relationship to study product	Related <input type="checkbox"/>
	Not related <input type="checkbox"/>

Record pertinent details for relationship assessment in "Comments".
 If "Not related", specify alternate etiology.

If etiology not known, enter "Unknown".

Action taken with study product	Dose not changed <input type="checkbox"/>
	Dose reduced <input type="checkbox"/>
	Dose increased <input type="checkbox"/>
	Drug withdrawn <input type="checkbox"/>
	Drug interrupted <input type="checkbox"/>
	Not applicable <input type="checkbox"/>

Action taken	<input type="checkbox"/>
--------------	--------------------------

Mark "None" or all that apply.

None

Medication(s)	<input type="checkbox"/>
Therapeutic procedure/surgery	<input type="checkbox"/>
Diagnostic procedure	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

Status/Outcome	Recovered/Resolved <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Recovered/Resolved with Sequelae <input type="checkbox"/>
	Not recovered/Not resolved <input type="checkbox"/>
	Fatal <input type="checkbox"/>
	Unknown <input type="checkbox"/>

Is this a serious adverse event (SAE) according to ICH/GCP or protocol guidelines?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

If "Yes", check all that apply.

Results in death	<input type="checkbox"/>
Is life-threatening	<input type="checkbox"/>

Form: Adverse Event

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

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: Non-Subject Specific Protocol Deviation Log

Site awareness date _____

Deviation date _____

Has or will this deviation be reported to the 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
 - 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 medications, 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 _____

Were specific PTID's affected? Yes
No

If "Yes", specify PTIDs _____

Plans and/or action taken to address the deviation _____

Plans and/or action taken to prevent future occurrences of the deviation _____

Deviation reported by _____

Add protocol deviations

Form: Protocol Deviations Y/N

Have any protocol deviations been reported?

Yes

No

If "Yes", update the Protocol Deviations log.

Form: Protocol Deviations

Site awareness date _____

Deviation date _____

Visit	V1 - Screening/Enrollment - C1/C2	<input type="checkbox"/>
	V2 - Day 8 - Phone Visit - C1	<input type="checkbox"/>
	V3 - Day 15 - C1	<input type="checkbox"/>
	V4 - Day 29 - C1	<input type="checkbox"/>
	V5 - Day 91 - C1	<input type="checkbox"/>
	V6 - Day 181 - C1	<input type="checkbox"/>
	V98 - Day 273 - C1	<input type="checkbox"/>
	V7 - Day 366 - C1	<input type="checkbox"/>
	V102 - Day 8 - Phone Visit - C2	<input type="checkbox"/>
	V103 - Day 29 - C2	<input type="checkbox"/>
	V104 - Day 36 - Phone Visit - C2	<input type="checkbox"/>
	V105 - Day 43 - C2	<input type="checkbox"/>
	V106 - Day 1B - C2	<input type="checkbox"/>
	V107 - Day 8B - Phone Visit - C2	<input type="checkbox"/>
	V108 - Day 15B - C2	<input type="checkbox"/>
	V109 - Day 29B - C2	<input type="checkbox"/>
	V110 - Day 91B - C2	<input type="checkbox"/>
	V111 - Day 181B - C2	<input type="checkbox"/>
	V112 - Day 366B - C2	<input type="checkbox"/>
	V113 - Day 1C - C2	<input type="checkbox"/>
	V114 - Day 8C - Phone Visit - C2	<input type="checkbox"/>
	V115 - Day 15C - C2	<input type="checkbox"/>
	V116 - Day 29C - C2	<input type="checkbox"/>
	V117 - Day 91C - C2	<input type="checkbox"/>
	V118 - Day 181C - C2	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

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	<input type="checkbox"/>
	Failure to follow randomization or blinding procedures	<input type="checkbox"/>
	Study product management deviation	<input type="checkbox"/>
	Study product dispensing error	<input type="checkbox"/>
	Study product use/non-use deviation	<input type="checkbox"/>

Form: Protocol Deviations

	Conduct of non-protocol procedure	<input type="checkbox"/>
	Improper AE/SAE	<input type="checkbox"/>
	Unreported AE	<input type="checkbox"/>
	Unreported SAE/AESI	<input type="checkbox"/>
	Breach of confidentiality	<input type="checkbox"/>
	Physical assessment deviation	<input type="checkbox"/>
	Lab assessment deviation	<input type="checkbox"/>
	Mishandled lab specimen	<input type="checkbox"/>
	Staff performing duties that they are not qualified to perform	<input type="checkbox"/>
	Use of non-IRB/EC-approved materials	<input type="checkbox"/>
	Use of excluded concomitant medications, devices, or non-study products	<input type="checkbox"/>
	Informed consent process deviation	<input type="checkbox"/>
	Visit completed outside of window	<input type="checkbox"/>
	Too few aliquots obtained	<input type="checkbox"/>
	Required procedure not conducted	<input type="checkbox"/>
	Other	<input type="checkbox"/>

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 <input type="radio"/>
	V2 - Day 8 - Phone Visit - C1 <input type="radio"/>
	V3 - Day 15 - C1 <input type="radio"/>
	V4 - Day 29 - C1 <input type="radio"/>
	V5 - Day 91 - C1 <input type="radio"/>
	V6 - Day 181 - C1 <input type="radio"/>
	V98 - Day 273 - C1 <input type="radio"/>
	V7 - Day 366 - C1 <input type="radio"/>
	V102 - Day 8 - Phone Visit - C2 <input type="radio"/>
	V103 - Day 29 - C2 <input type="radio"/>
	V104 - Day 36 - Phone Visit - C2 <input type="radio"/>
	V105 - Day 43 - C2 <input type="radio"/>
	V106 - Day 1B - C2 <input type="radio"/>
	V107 - Day 8B - Phone Visit - C2 <input type="radio"/>
	V108 - Day 15B - C2 <input type="radio"/>
	V109 - Day 29B - C2 <input type="radio"/>
	V110 - Day 91B - C2 <input type="radio"/>
	V111 - Day 181B - C2 <input type="radio"/>
	V112 - Day 366B - C2 <input type="radio"/>
	V113 - Day 1C - C2 <input type="radio"/>
	V114 - Day 8C - Phone Visit - C2 <input type="radio"/>
	V115 - Day 15C - C2 <input type="radio"/>
	V116 - Day 29C - C2 <input type="radio"/>
	V117 - Day 91C - C2 <input type="radio"/>
	V118 - Day 181C - C2 <input type="radio"/>
	Interim Visit <input type="radio"/>

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 <input type="radio"/>
	Initial ultrasound <20 weeks <input type="radio"/>
	Initial ultrasound >= 20 weeks <input type="radio"/>
	Physical examination <input type="radio"/>
	Conception date by assisted reproduction <input type="radio"/>
	Other <input type="radio"/>

Form: Pregnancy Report

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? Yes

If "No", end of form. 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 Full term live birth (greater than or equal to 37 weeks)
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" 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. Yes
No
 If "No" or "Unknown", go to "Complete the infant items below for live births only." 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	<input type="checkbox"/>
Central nervous system, spinal	<input type="checkbox"/>
Cardiovascular	<input type="checkbox"/>
Renal	<input type="checkbox"/>
Gastrointestinal	<input type="checkbox"/>
Pulmonary	<input type="checkbox"/>
Musculoskeletal/extremities	<input type="checkbox"/>
Physical defect	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Genitourinary	<input type="checkbox"/>
Chromosomal	<input type="checkbox"/>
Cranio-facial (structural)	<input type="checkbox"/>
Hematologic	<input type="checkbox"/>
Infectious	<input type="checkbox"/>
Endocrine/metabolic	<input type="checkbox"/>
Other	<input type="checkbox"/>

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. Male
Female
Intersex
 Infant sex 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	<input type="checkbox"/>
	Atlanta - ECC VTEU	<input type="checkbox"/>
	Cincinnati - VTEU	<input type="checkbox"/>
	Galveston - UTMB VTEU	<input type="checkbox"/>
	Houston - VTEU	<input type="checkbox"/>
	Mineola	<input type="checkbox"/>
	New York - Bellevue	<input type="checkbox"/>
	Pittsburgh - Vanderbilt VTEU	<input type="checkbox"/>
	Rochester - VTEU	<input type="checkbox"/>
	Seattle - Kaiser VTEU	<input type="checkbox"/>
	Seattle - UW VTEU	<input type="checkbox"/>
	University of Maryland Baltimore	<input type="checkbox"/>
	VTEU	<input type="checkbox"/>

Name of receiving study site	Atlanta - VTEU	<input type="checkbox"/>
	Atlanta - ECC VTEU	<input type="checkbox"/>
	Cincinnati - VTEU	<input type="checkbox"/>
	Galveston - UTMB VTEU	<input type="checkbox"/>
	Houston - VTEU	<input type="checkbox"/>
	Mineola	<input type="checkbox"/>
	New York - Bellevue	<input type="checkbox"/>
	Pittsburgh - Vanderbilt VTEU	<input type="checkbox"/>
	Rochester - VTEU	<input type="checkbox"/>
	Seattle - Kaiser VTEU	<input type="checkbox"/>
	Seattle - UW VTEU	<input type="checkbox"/>
	University of Maryland Baltimore	<input type="checkbox"/>
	VTEU	<input type="checkbox"/>

Visit of last completed contact with participant	V1 - Screening/Enrollment - C1/C2	<input type="checkbox"/>
	V2 - Day 8 - Phone Visit - C1	<input type="checkbox"/>
	V3 - Day 15 - C1	<input type="checkbox"/>
	V4 - Day 29 - C1	<input type="checkbox"/>
	V5 - Day 91 - C1	<input type="checkbox"/>
	V6 - Day 181 - C1	<input type="checkbox"/>
	V98 - Day 273 - C1	<input type="checkbox"/>
	V7 - Day 366 - C1	<input type="checkbox"/>
	V102 - Day 8 - Phone Visit - C2	<input type="checkbox"/>
	V103 - Day 29 - C2	<input type="checkbox"/>
	V104 - Day 36 - Phone Visit - C2	<input type="checkbox"/>
	V105 - Day 43 - C2	<input type="checkbox"/>
	V106 - Day 1B - C2	<input type="checkbox"/>

Form: Participant Transfer

	V107 - Day 8B - Phone Visit - C2	<input type="checkbox"/>
	V108 - Day 15B - C2	<input type="checkbox"/>
	V109 - Day 29B - C2	<input type="checkbox"/>
	V110 - Day 91B - C2	<input type="checkbox"/>
	V111 - Day 181B - C2	<input type="checkbox"/>
	V112 - Day 366B - C2	<input type="checkbox"/>
	V113 - Day 1C - C2	<input type="checkbox"/>
	V114 - Day 8C - Phone Visit - C2	<input type="checkbox"/>
	V115 - Day 15C - C2	<input type="checkbox"/>
	V116 - Day 29C - C2	<input type="checkbox"/>
	V117 - Day 91C - C2	<input type="checkbox"/>
	V118 - Day 181C - C2	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

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	<input type="checkbox"/>
	Atlanta - ECC VTEU	<input type="checkbox"/>
	Cincinnati - VTEU	<input type="checkbox"/>
	Galveston - UTMB VTEU	<input type="checkbox"/>
	Houston - VTEU	<input type="checkbox"/>
	Mineola	<input type="checkbox"/>
	New York - Bellevue	<input type="checkbox"/>
	Pittsburgh - Vanderbilt VTEU	<input type="checkbox"/>
	Rochester - VTEU	<input type="checkbox"/>
	Seattle - Kaiser VTEU	<input type="checkbox"/>
	Seattle - UW VTEU	<input type="checkbox"/>
	University of Maryland Baltimore VTEU	<input type="checkbox"/>

Name of transferring study site	Atlanta - VTEU	<input type="checkbox"/>
	Atlanta - ECC VTEU	<input type="checkbox"/>
	Cincinnati - VTEU	<input type="checkbox"/>
	Galveston - UTMB VTEU	<input type="checkbox"/>
	Houston - VTEU	<input type="checkbox"/>
	Mineola	<input type="checkbox"/>
	New York - Bellevue	<input type="checkbox"/>
	Pittsburgh - Vanderbilt VTEU	<input type="checkbox"/>
	Rochester - VTEU	<input type="checkbox"/>
	Seattle - Kaiser VTEU	<input type="checkbox"/>
	Seattle - UW VTEU	<input type="checkbox"/>
	University of Maryland Baltimore VTEU	<input type="checkbox"/>

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 <input type="checkbox"/>
	Death <input type="checkbox"/>
	Voluntary withdrawal by subject <input type="checkbox"/>
	Investigator decision <input type="checkbox"/>
	Lost to follow up <input type="checkbox"/>
	Termination of site by sponsor <input type="checkbox"/>
	Protocol deviation <input type="checkbox"/>
	Adverse event (not including death) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Study terminated by sponsor <input type="checkbox"/>
	Participant unable to adhere to visit schedule <input type="checkbox"/>
	Participant relocated, no follow-up planned <input type="checkbox"/>
	Reactogenicity symptom <input type="checkbox"/>
	Became inelligible after enrollment <input type="checkbox"/>
	Confirmed SARS CoV-2 infection <input type="checkbox"/>
	Receipt of SARS-CoV-2 vaccine outside of study <input type="checkbox"/>
	Other, specify <input type="checkbox"/>
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	<input type="radio"/>
Death	<input type="radio"/>
Voluntary withdrawal by subject	<input type="radio"/>
Investigator decision	<input type="radio"/>
Lost to follow-up	<input type="radio"/>
Termination of site by sponsor	<input type="radio"/>
Protocol deviation	<input type="radio"/>
Adverse event (not including death)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Study terminated by sponsor	<input type="radio"/>
Participant unable to adhere to visit schedule	<input type="radio"/>
Participant relocated, no follow-up planned	<input type="radio"/>
Reactogenicity symptom	<input type="radio"/>
Became ineligible after enrollment	<input type="radio"/>
Confirmed SARS CoV-2 infection	<input type="radio"/>
Cohort 1 group 4E Participant rolled over into Cohort 1 group 15E	<input type="radio"/>
Other, specify	<input type="radio"/>

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. _____
