

Subject Case Report Forms

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Participant Identifier**

**Generated On: 23 Feb 2022 01:05:51**

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Participant ID: \_\_\_\_\_

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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

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL  
Form: Screening Date of Visit  
Generated On: 23 Feb 2022 01:05:51

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

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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 \_\_\_\_\_

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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 - 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"/>

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Form: Follow-up Visit Summary

Generated On: 23 Feb 2022 01:05:51

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.

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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

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

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Informed Consent**

**Generated On: 23 Feb 2022 01:05:51**

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Informed consent date \_\_\_\_\_

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Was consent provided for specimen storage/use in secondary research?

Yes

No

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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 \_\_\_\_\_

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

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 COVID-19 vaccine under EUA dosing guidelines at least 12 weeks and no more than 20 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.

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

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If "Investigator decision", specify (max. 200 characters): \_\_\_\_\_

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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-19; 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-19; Janssen –  
Ad26.COVID-19 booster

5E: Previously dosed Moderna –   
mRNA-1273; Janssen –  
Ad26.COVID-19 booster

6E: Previously dosed   
Pfizer/BioNTech – BNT162b2;  
Janssen – Ad26.COVID-19 booster

7E: Previously dosed Janssen –   
Ad26.COVID-19; 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-19; Moderna –  
mRNA-1273.211 booster

11E: Previously dosed   
Pfizer/BioNTech – BNT162b2;  
Moderna – mRNA-1273.211  
booster

12E: Previously dosed Janssen –   
Ad26.COVID-19; 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-19; Novavax –  
NVX-CoV2373 booster

16E: Previously dosed Moderna   
– mRNA-1273; Novavax –  
NVX-CoV2373 booster

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Form: Enrollment

Generated On: 23 Feb 2022 01:05:51

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

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If this participant is enrolling in Cohort 1, group "15E: Previously dosed Janssen – Ad26.COVID-S; Novavax – NVX-CoV2373 booster", was this participant previously enrolled in Cohort 1, Group "4E: Previously dosed Janssen – Ad26.COVID-S; Janssen – Ad26.COVID-S booster"?

Yes   
No

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If yes, provide this participant's PTID for group 4E \_\_\_\_\_

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How was vaccination information obtained?

Vaccination card

Medical records

Participant report

Other

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If "Other", specify \_\_\_\_\_

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Vaccine manufacturer

Pfizer/BioNTech - BNT162b2

Moderna - mRNA-1273

Janssen - Ad26.COV2-S

Other

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If "Other", specify \_\_\_\_\_

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Date of first vaccination \_\_\_\_\_

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Date of second vaccination, if applicable \_\_\_\_\_

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Form: Vaccination - Enrollment

Generated On: 23 Feb 2022 01:05:51

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): \_\_\_\_\_

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Form: Vaccination - Follow Up

Generated On: 23 Feb 2022 01:05:51

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

Generated On: 23 Feb 2022 01:05:51

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   
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): \_\_\_\_\_

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

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): \_\_\_\_\_

Were vital signs done? Yes

No

Date of assessment \_\_\_\_\_ Fixed Unit: C

Body temperature \_\_\_\_\_ Fixed Unit: C

Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Pulse \_\_\_\_\_ Fixed Unit: beats/min

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Form: Vital Signs - Post Vacc

Generated On: 23 Feb 2022 01:05:51

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

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

Generated On: 23 Feb 2022 01:05:51

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 \_\_\_\_\_

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): \_\_\_\_\_

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

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**Form: Additional Study Procedures**

**Generated On: 23 Feb 2022 01:05:51**

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Select any additional forms completed at this visit.

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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 - 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"/>
Missed Study Product Administration	<input type="checkbox"/>

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Form: Reactogenicity - Baseline and Early  
Generated On: 23 Feb 2022 01:05:51

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

---

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

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 Fixed Unit: cm

---

Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)

---

---

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 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 Not assessed

---

Malaise and/or fatigue None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Myalgia/body aches None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Arthralgia/joint pain None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Headache None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Nausea 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

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

---

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**  
**Form: Reactogenicity - Baseline and Early**  
**Generated On: 23 Feb 2022 01:05:51**

Potentially life-threatening

Adverse event

Comments (max. 450 characters):

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

---

	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"/>
	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   
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

---

	Day 5	<input type="checkbox"/>
	Day 6	<input type="checkbox"/>
	Day 7	<input type="checkbox"/>
	Day 8	<input type="checkbox"/>

---

Date of assessment \_\_\_\_\_

Body temperature \_\_\_\_\_ Fixed Unit: C

---

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"/>

---

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"/>

---

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"/>

---

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"/>

---

Adverse event \_\_\_\_\_

---

Arthralgia/joint pain	Not assessed	<input type="checkbox"/>
	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>

---

---

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   
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

---

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 Not assessed

---

Malaise and/or fatigue None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Myalgia/body aches None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Arthralgia/joint pain None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Headache None

Mild

Moderate

Severe

Potentially life-threatening

---

Adverse event Not assessed

---

Nausea 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

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

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 <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"/>

---

---

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

---

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 \_\_\_\_\_

---

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"/>

---

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

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

---

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

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

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	<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"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

---

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

---

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"/>

---

---

	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"/>

---

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

---

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL

Form: Reactogenicity - Daily Log

Generated On: 23 Feb 2022 01:05:51

---

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

Generated On: 23 Feb 2022 01:05:51

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 \_\_\_\_\_

---

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

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):	

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL

Form: Missed Visit

Generated On: 23 Feb 2022 01:05:51

---

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) \_\_\_\_\_

---

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): \_\_\_\_\_

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL

Form: Study Product Administration Error

Generated On: 23 Feb 2022 01:05:51

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): \_\_\_\_\_

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**  
**Form: Specimen Collection - NP/Nasal Swab**  
**Generated On: 23 Feb 2022 01:05:51**

---

Was specimen collected? Yes

No

---

If "No", provide reason and end of form. Participant declined

Participant unable to provide sample

Other

Primary reason specimen was not collected \_\_\_\_\_

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): \_\_\_\_\_

---

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Form: SARS-CoV-2 Test Results

Generated On: 23 Feb 2022 01:05:51

---

Specimen collection date

---

Test result

Positive

Negative

Indeterminate

---

Test type

Molecular

Antigen

Unknown

---

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Medical History Y/N**

**Generated On: 23 Feb 2022 01:05:51**

---

Does the participant have any medical history to report?

Yes

No

---

If "Yes", update the Medical History log.

---

IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL

Form: Medical History

Generated On: 23 Feb 2022 01:05:51

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): \_\_\_\_\_

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Concomitant Medications Y/N**

**Generated On: 23 Feb 2022 01:05:51**

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Were any concomitant medications taken?

Yes

No

---

If "Yes", update the Concomitant Medications log.

---

Form: Concomitant Medications

Generated On: 23 Feb 2022 01:05:51

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

---

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. \_\_\_\_\_

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Adverse Event Y/N**

**Generated On: 23 Feb 2022 01:05:51**

---

Has the participant experienced an adverse event during the study?

Yes

No

---

If "Yes", update the Adverse Event log.

---

Form: Adverse Event

Generated On: 23 Feb 2022 01:05:51

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".

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

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   
No

If "Yes", check all that apply.

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

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Form: Adverse Event

Generated On: 23 Feb 2022 01:05:51

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

Was this AE a worsening of a baseline medical condition? Yes   
No

Comments (max. 450 characters): \_\_\_\_\_

**IDCRC21-0012\_Version\_11.0\_PROD\_EC\_18FEB2022: ALL**

**Form: Protocol Deviations Y/N**

**Generated On: 23 Feb 2022 01:05:51**

---

Have any protocol deviations been reported?

Yes

No

---

If "Yes", update the Protocol Deviations log.

---

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

---

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	_____

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 \_\_\_\_\_

Amenorrhic 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. \_\_\_\_\_

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

Generated On: 23 Feb 2022 01:05:51

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

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:

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

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. Male

Female

Intersex

Infant sex Decline to answer

Infant birth weight Fixed Unit: kg

Or \_\_\_\_\_

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

---

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

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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

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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

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Form: Participant Transfer

Generated On: 23 Feb 2022 01:05:51

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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 \_\_\_\_\_

---

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

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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

---

---

Date of study product completion or discontinuation	
Primary reason for ending study product use	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 inelligible after enrollment <input type="radio"/>
	Confirmed SARS CoV-2 infection <input type="radio"/>
	Receipt of SARS-CoV-2 vaccine outside of study <input type="radio"/>
	Other, specify <input type="radio"/>
<hr/>	
If "Other", specify (max. 200 characters):	
<hr/>	
If "Adverse Event" or "Death" or "Confirmed SARS CoV-2 infection", select applicable event.	
<hr/>	

---

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. \_\_\_\_\_

---