

US3212182 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3212182

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 11 Aug 2021 22:11:25

Participant ID

US3212182

[mRNA-1273-P301 Completion Guidelines](#)

US3212182

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3212182

Folder: Screening

Form: Demographics

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	20
Age Units	YEARS
Age (Derived)	20
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	True

US3212182

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3212182

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3212182

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:22
Height (xxx.x)	62 in
Weight (xxx.x)	124.2 lb
BMI (xxx.x)	22.76398 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Date of assessment (dd MMM yyyy) 14 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 14 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 02 Apr 2021 20:11:58

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☒ No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify (b) (6) BARISTA

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 02 Apr 2021 20:11:58

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PARTICIPANT GOES IN PERSON TO THEIR MAIN WORKPLACE MORE THAN 2 DAYS/WEEK. PARTICIPANT INTERACTS WITH 5 OR MORE PEOPLE IN PERSON DURING THE COURSE OF A TYPICAL WORKDAY...

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104507

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:22
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 15:38
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 AUG 2020

What was the treatment time? (00:00-23:59) 15:02 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 15:02

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 14 AUG 2020

Collection time (00:00-23:59) 13:59 (24 HR)

Collection date and time (derived) 14 AUG 2020 13:59

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:48	14 AUG 2020 13:48
Nasopharyngeal Swab 2	No		

US3212182

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

14 AUG 2020 15:33

PC Open Date & Time

14 AUG 2020 15:22

PC Close Date & Time

14 AUG 2020 17:52

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	14 AUG 2020 19:00
PC Open Date & Time	14 AUG 2020 18:47
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 12:18

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

18 AUG 2020 00:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

19 AUG 2020 00:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

20 AUG 2020 01:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

20 AUG 2020 20:34

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 15:35

PC Open Date & Time

14 AUG 2020 15:22

PC Close Date & Time

14 AUG 2020 17:52

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:00

PC Open Date & Time

14 AUG 2020 18:47

PC Close Date & Time

15 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:10

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:03

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 00:03

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 00:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 01:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 20:34

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 15:36
PC Open Date & Time	14 AUG 2020 15:22
PC Close Date & Time	14 AUG 2020 17:52

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:01
PC Open Date & Time	14 AUG 2020 18:47
PC Close Date & Time	15 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:10
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

49 of 2105

EAB) (1725)

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:03
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

51 of 2105

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 00:04
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 00:01
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

55 of 2105

EAB) (1725)

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 01:35
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:34
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3212182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:09
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3212182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☒
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3212182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 SEP 2020
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Collection time (00:00-23:59)	13:48 (24 HR)
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Collection date and time (derived)	11 SEP 2020 13:48
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US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:43	11 SEP 2020 13:43
Nasopharyngeal Swab 2	No		

US3212182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:58

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 12:23
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	13:16 (24 HR)
Collection date and time (derived)	09 OCT 2020 13:16

US3212182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 OCT 2020 11:54:29
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 OCT 2020 12:05:50

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 OCT 2020 15:56:44
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 NOV 2020 11:59:31

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 NOV 2020 18:03:17

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 11:59:21
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 12:08:04
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 DEC 2020 12:02:13
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 12:11:12
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 JAN 2021 11:59:17

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 01:18:45
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately



Date and time of submission	31 JAN 2021 15:59:12
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 FEB 2021 21:38:59
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 12:43:44
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 MAR 2021 09:12:41

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 09:58:41
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

14 APR 2021 18:06:35

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 APR 2021 02:37:01

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

29 APR 2021 11:59:13

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	24 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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17 FEB 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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03 MAR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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17 MAR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3212182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:11:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 12:43:51

US3212182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 JAN 2021

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments CALLED FOR SAFETY CALL, NO
ANSWER, LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	18 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 MAR 2021
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 08:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 18 MAR 2021

Collection time (00:00-23:59) 09:45 (24 HR)

Collection date and time (derived) 18 MAR 2021 09:45

US3212182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:59

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 19:10:43

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 19:10:43

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212182

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212182

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Date of Contact	1 FEB 2021
Time of Contact	14:22
Date and Time of Contact (derived)	1 FEB 2021 14:22
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input checked="" 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 type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Date of Visit 28 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 28 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed CVS MINUTECLINIC, 602 W
GRAND PKWY S, KATY TX
77494
LUMIRADX SARS-COV-2 AG
TEST

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 18 MAR 2021

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☒

Folder OID UNBLND_DECIDE

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	<input type="checkbox"/>
Continuing with mRNA-1273	<input type="checkbox"/>

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00 - 23:59)	09:40
Collection Date and Time (derived)	18 MAR 2021 09:40

US3212182

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID

Adverse event

MORNING SICKNESS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID

Adverse event

GROUP B STREPTOCOCCAL
INFECTION (GBS POSITIVE)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID	
Adverse event	HYPEREMESIS GRAVIDARUM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID	
Adverse event	CHRONIC COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 18:13:27

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID	
Adverse event	IRON DEFICIENCY ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID	USA-US115-2021-MRNA-1273-P30 1000018
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	28 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

SUBJECT WAS SCHEDULED FOR
ILLNESS VISIT ON 02FEB2021.
SHE DID NOT ARRIVE FOR THE
APPOINTMENT AND WAS
CONTACTED ON 2FEB2021 @
1036, 3FEB2021 @1720, AND
4FEB2021 @1343 TO SCHEDULE
ILLNESS VISIT, NO REPLY.
ACTION TAKEN FOR MISSED
ILLNESS VISIT - SUBJECT WAS
REACHED TODAY 12MAR2021
FOR MISSED EDIARY AND
RE-EDUCATED/ RETRAINED TO
COMPLY WITH STUDY VISITS.
SUBJECT VERBALIZED
UNDERSTANDING. SHE DID
TEST POSITIVE FOR COVID19
ON 28JAN WITH AN OUTSIDE
STUDY TEST AND TESTED
NEGATIVE ON 06FEB.
BECAUSE SUBJECT WAS NOT
COMPLIANT IN ATTENDING
ILLNESS VISIT, THE VISIT WAS
NOT PERFORMED AND ILLNESS
VISIT FOLDER WILL REMAIN
EMPTY.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

AEID

Adverse event

GASTROENTERITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 18:13:27

Generated On: 11 Aug 2021 22:11:25

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA RESCUE

Dose per administration 90

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication PRENATAL VITAMIN

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication PENICILLIN VK

Prophylaxis Yes ☐
No ☒

Indication GROUP B STREPTOCOCCAL
INFECTION (GBS POSITIVE)

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 14:52:51

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication UNKNOWN COUGH DROPS

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication CHILDREN'S DIMETAPP

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 20

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 14:52:51

Generated On: 11 Aug 2021 22:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212182

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3212182

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

Date of dosing discontinuation (dd MMM yyyy) 11 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3212182

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:11:25

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

SAEID	USA-US115-2021-MRNA-1273-P301000018
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:11:57

Generated On: 11 Aug 2021 22:11:25

SAEID	USA-US115-2021-MRNA-1273-P301000018
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/MAR/2021 15:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3212182 (Prod: DM Clinical Research - ERN - PPDS)

US3212182

Form: Participant Creation

Generated On: 11 Aug 2021 22:11:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'US3212182'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:17

US3212182

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:44:58

US3212182

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:18

US3212182

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	14 Aug 2020 18:44:58

US3212182

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'SCRN'	System	14 Aug 2020 18:44:58

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered (b) (6) 2000'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:19

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '20'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'YEARS'	System	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '20'	System	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Female (F)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:14

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Aug 2020'	System	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2020'	System	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Amendment 2 (2)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:25

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:18

US3212182

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'I'	System	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:11:25

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:11:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:43

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 18:47:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 18:47:18
Data point term sent to Coder	System	14 Aug 2020 18:46:25
User entered 'MILD ASTHMA'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'UN UNK 2002'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Jan 2002'	System	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2002'	System	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered empty.	System	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered empty.	System	14 Aug 2020 18:45:56

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'If the appendectomy was a result of appendicitis please add to the log. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:56:34
Query 'If the appendectomy was a result of appendicitis please add to the log. ' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	16 Sep 2020 19:32:48
User opened query 'If the appendectomy was a result of appendicitis please add to the log. ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 22:49:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:47:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 18:47:18
Data point term sent to Coder	System	14 Aug 2020 18:46:26
User entered 'APPENDECTOMY'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'UN UNK 2016'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'UN UNK 2016'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Jan 2016'	System	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2016'	System	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Jan 2016'	System	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2016'	System	14 Aug 2020 18:46:11

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:34:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:34:50
Data point term sent to Coder	System	16 Sep 2020 19:33:51
User entered 'APPENDICITIS'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'UN UNK 2016'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Un UNK 2016'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Jan 2016'	System	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2016'	System	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'Jan 2016'	System	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:11:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '2016'	System	16 Sep 2020 19:33:22

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '12:22'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '62' in	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24
DataPoint set to visible.	(b) (4) System	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '124.2' lb	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24
DataPoint set to visible.	(b) (4) System	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
Amendment Manager: User entered '22.76398'	System	16 Sep 2020 23:57:48
User entered '22.8'	System	14 Aug 2020 18:48:24
DataPoint set to visible.	System	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'kg/m2'	System	14 Aug 2020 18:48:24
DataPoint set to visible.	System	14 Aug 2020 18:45:32

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 18:41:14
User entered 'Other (Other)'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 18:41:14
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'bpm'	System	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'breaths/min'	System	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'mmHg'	System	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered 'mmHg'	System	14 Aug 2020 18:48:24

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33

US3212182

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33

US3212182

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:32

US3212182

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 15:09:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 19:06:42
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:32

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:11:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:48:44

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Urine (URINE)'	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Negative (NEGATIVE)'	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User entered empty.	System	14 Aug 2020 18:49:01

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered (b) (6) BARISTA'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:33
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Participant goes in person to their main workplace more than 2 days/week. Participant interacts with 5 or more people in person during the course of a typical workday...'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:00

US3212182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:45

US3212182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:45

US3212182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:45

US3212182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT1'	System	14 Aug 2020 18:50:45

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:22

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:39:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:39:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:44:22
User entered '104507' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:22

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:44:22

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 19:31:53

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 19:31:53

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 19:31:53

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 19:31:53

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 19:31:53

US3212182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:25

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:56:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:22:38

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '12:22'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '98' F	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '62'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '15'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '105'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '69'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:33:48
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.' (Site from System).	Afifah Ayub (b) (4)	14 Aug 2020 20:54:27
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 20:54:14
User entered '15:38'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '14 Aug 2020 15:38'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '97.6' F	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '77'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '112'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '62'	Afifah Ayub (b) (4)	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	14 Aug 2020 20:54:14

US3212182

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:50:53

US3212182

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:50:53

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Oct 2020 17:15:59
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	14 Aug 2020 18:51:01

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '15:02'	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '14 Aug 2020 15:02'	System	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'ONCE'	System	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 20:04:40

US3212182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:33

US3212182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:33

US3212182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13:59'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:33

US3212182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '14 Aug 2020 13:59'	System	14 Aug 2020 19:52:33

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13:48'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '14 Aug 2020 13:48'	System	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:10:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:10:38
User entered '13:48'	Afifah Ayub (b) (4)	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	25 Aug 2020 21:10:38
User entered '14 Aug 2020 13:48'	System	14 Aug 2020 19:52:48

US3212182

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 20:42:53

US3212182

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	18 Aug 2020 20:42:53

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:32:57', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6d185c4d-7456-44e5-987b-0e53bab031fe' User entered 'Yes (Y)'	System	14 Aug 2020 20:33:29
	System	14 Aug 2020 20:33:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:33:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6d185c4d-7456-44e5-987b-0e53bab031fe' User entered '97.6'	System	14 Aug 2020 20:33:29
	System	14 Aug 2020 20:33:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:33:20', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6d185c4d-7456-44e5-987b-0e53bab031fe' User entered 'No (N)'	System	14 Aug 2020 20:33:29
	System	14 Aug 2020 20:33:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:33:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6d185c4d-7456-44e5-987b-0e53bab031fe' User entered '14 Aug 2020 15:33'	System	14 Aug 2020 20:33:29
	System	14 Aug 2020 20:33:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 15:22'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 17:52'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd7e12443-5d76-40c7-924b-e387e86f1376' User entered 'Yes (Y)'	System	15 Aug 2020 00:00:17
	System	15 Aug 2020 00:00:17

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:07', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd7e12443-5d76-40c7-924b-e387e86f1376' User entered '97.6'	System	15 Aug 2020 00:00:17
	System	15 Aug 2020 00:00:17

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:12', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd7e12443-5d76-40c7-924b-e387e86f1376'	System	15 Aug 2020 00:00:17
User entered 'No (N)'	System	15 Aug 2020 00:00:17

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd7e12443-5d76-40c7-924b-e387e86f1376'	System	15 Aug 2020 00:00:17
User entered '14 Aug 2020 19:00'	System	15 Aug 2020 00:00:17

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 18:47'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 2'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:17:27', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '10b74659-fe89-4208-97ce-4cddebde11dc' User entered 'Yes (Y)'	System	15 Aug 2020 17:18:29
	System	15 Aug 2020 17:18:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:17:32', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '10b74659-fe89-4208-97ce-4cddebde11dc' User entered '98.5'	System	15 Aug 2020 17:18:29
	System	15 Aug 2020 17:18:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:18:21', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '10b74659-fe89-4208-97ce-4cddebde11dc' User entered 'No (N)'	System	15 Aug 2020 17:18:29
	System	15 Aug 2020 17:18:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:18:27', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '10b74659-fe89-4208-97ce-4cddebde11dc' User entered '15 Aug 2020 12:18'	System	15 Aug 2020 17:18:29
	System	15 Aug 2020 17:18:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 3'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:08', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a180ced2-c93a-485a-a8e8-2e8f83b0c7a9' User entered 'Yes (Y)'	System	16 Aug 2020 17:02:30
	System	16 Aug 2020 17:02:30

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:18', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a180ced2-c93a-485a-a8e8-2e8f83b0c7a9' User entered '97.9'	System	16 Aug 2020 17:02:30
	System	16 Aug 2020 17:02:30

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:22', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a180ced2-c93a-485a-a8e8-2e8f83b0c7a9'	System	16 Aug 2020 17:02:30
User entered 'No (N)'	System	16 Aug 2020 17:02:30

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:27', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a180ced2-c93a-485a-a8e8-2e8f83b0c7a9' User entered '16 Aug 2020 12:02'	System	16 Aug 2020 17:02:30
	System	16 Aug 2020 17:02:30

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 4'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:04:14', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6d71d3b-473f-4897-bffe-2c1b828cbb39' User entered 'Yes (Y)'	System	18 Aug 2020 05:05:29
	System	18 Aug 2020 05:05:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:05:21', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6d71d3b-473f-4897-bffe-2c1b828cbb39' User entered '97.6'	System	18 Aug 2020 05:05:29
	System	18 Aug 2020 05:05:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:05:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6d71d3b-473f-4897-bffe-2c1b828cbb39'	System	18 Aug 2020 05:05:29
User entered 'No (N)'	System	18 Aug 2020 05:05:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:05:28', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6d71d3b-473f-4897-bffe-2c1b828cbb39' User entered '18 Aug 2020 00:05'	System	18 Aug 2020 05:05:29
	System	18 Aug 2020 05:05:29

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 5'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T23:59:54', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ad503908-6248-47f3-8d4a-e6474438508e' User entered 'Yes (Y)'	System	19 Aug 2020 05:01:02
	System	19 Aug 2020 05:01:02

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:31', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ad503908-6248-47f3-8d4a-e6474438508e' User entered '97.7'	System	19 Aug 2020 05:01:02
	System	19 Aug 2020 05:01:02

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:38', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ad503908-6248-47f3-8d4a-e6474438508e' User entered 'No (N)'	System	19 Aug 2020 05:01:02
	System	19 Aug 2020 05:01:02

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:40', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ad503908-6248-47f3-8d4a-e6474438508e' User entered '19 Aug 2020 00:00'	System	19 Aug 2020 05:01:02
	System	19 Aug 2020 05:01:02

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 6'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:34:31', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8a50f687-8b5f-40b4-8b6a-5a0816e701ba' User entered 'Yes (Y)'	System	20 Aug 2020 06:34:54
	System	20 Aug 2020 06:34:54

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:34:47', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8a50f687-8b5f-40b4-8b6a-5a0816e701ba' User entered '96.9'	System	20 Aug 2020 06:34:54
	System	20 Aug 2020 06:34:54

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:34:49', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8a50f687-8b5f-40b4-8b6a-5a0816e701ba'	System	20 Aug 2020 06:34:54
User entered 'No (N)'	System	20 Aug 2020 06:34:54

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:34:52', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8a50f687-8b5f-40b4-8b6a-5a0816e701ba' User entered '20 Aug 2020 01:34'	System	20 Aug 2020 06:34:54
	System	20 Aug 2020 06:34:54

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 7'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f211fb9b-87e4-4104-adcb-419d565f39a7' User entered 'Yes (Y)'	System	21 Aug 2020 01:34:39
	System	21 Aug 2020 01:34:39

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:30', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f211fb9b-87e4-4104-adcb-419d565f39a7' User entered '97.4'	System	21 Aug 2020 01:34:39
	System	21 Aug 2020 01:34:39

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:35', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f211fb9b-87e4-4104-adcb-419d565f39a7'	System	21 Aug 2020 01:34:39
User entered 'No (N)'	System	21 Aug 2020 01:34:39

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:36', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f211fb9b-87e4-4104-adcb-419d565f39a7' User entered '20 Aug 2020 20:34'	System	21 Aug 2020 01:34:39
	System	21 Aug 2020 01:34:39

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:34:03', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6576d7de-066d-41d6-b4ec-fac896d9cdf'	System	14 Aug 2020 20:35:20
User entered 'None (1)'	System	14 Aug 2020 20:35:20

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:34:06', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6576d7de-066d-41d6-b4ec-fac896d9cdf'	System	14 Aug 2020 20:35:20
User entered 'No (N)'	System	14 Aug 2020 20:35:20

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:34:14', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6576d7de-066d-41d6-b4ec-fac896d9cdf'	System	14 Aug 2020 20:35:20
User entered 'No (N)'	System	14 Aug 2020 20:35:20

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:09', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6576d7de-066d-41d6-b4ec-fac896d9cdff'	System	14 Aug 2020 20:35:20
User entered 'None (1)'	System	14 Aug 2020 20:35:20

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '6576d7de-066d-41d6-b4ec-fac896d9cdf'	System	14 Aug 2020 20:35:20
User entered '14 Aug 2020 15:35'	System	14 Aug 2020 20:35:20

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 15:22'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 17:52'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:31', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8bdd229f-a16e-46f8-ac21-dc8d69ddd4c3'	System	15 Aug 2020 00:00:57
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 00:00:57

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:33', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8bdd229f-a16e-46f8-ac21-dc8d69ddd4c3' User entered 'No (N)'	System	15 Aug 2020 00:00:57
	System	15 Aug 2020 00:00:57

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:36', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8bdd229f-a16e-46f8-ac21-dc8d69ddd4c3' User entered 'No (N)'	System	15 Aug 2020 00:00:57
	System	15 Aug 2020 00:00:57

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8bdd229f-a16e-46f8-ac21-dc8d69ddd4c3'	System	15 Aug 2020 00:00:57
User entered 'None (1)'	System	15 Aug 2020 00:00:57

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:52', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '8bdd229f-a16e-46f8-ac21-dc8d69ddd4c3' User entered '14 Aug 2020 19:00'	System	15 Aug 2020 00:00:57
	System	15 Aug 2020 00:00:57

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 18:47'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 2'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:09:27', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4bfa2046-c227-4e89-a5ea-efefdb38322b'	System	15 Aug 2020 17:10:33
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 17:10:33

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:10', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4bfa2046-c227-4e89-a5ea-efefdb38322b' User entered 'No (N)'	System	15 Aug 2020 17:10:33
	System	15 Aug 2020 17:10:33

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4bfa2046-c227-4e89-a5ea-efefdb38322b' User entered 'No (N)'	System	15 Aug 2020 17:10:33
	System	15 Aug 2020 17:10:33

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:24', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4bfa2046-c227-4e89-a5ea-efefdb38322b' User entered 'None (1)'	System	15 Aug 2020 17:10:33
	System	15 Aug 2020 17:10:33

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:29', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4bfa2046-c227-4e89-a5ea-efefdb38322b' User entered '15 Aug 2020 12:10'	System	15 Aug 2020 17:10:33
	System	15 Aug 2020 17:10:33

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 3'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:51', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '139f38de-ffed-46c6-824b-9306c66140fb' User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:03:17
	System	16 Aug 2020 17:03:17

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:02:56', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '139f38de-ffed-46c6-824b-9306c66140fb' User entered 'No (N)'	System	16 Aug 2020 17:03:17
	System	16 Aug 2020 17:03:17

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:05', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '139f38de-ffed-46c6-824b-9306c66140fb' User entered 'No (N)'	System	16 Aug 2020 17:03:17
	System	16 Aug 2020 17:03:17

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:10', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '139f38de-ffed-46c6-824b-9306c66140fb' User entered 'None (1)'	System	16 Aug 2020 17:03:17
	System	16 Aug 2020 17:03:17

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:14', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '139f38de-ffed-46c6-824b-9306c66140fb' User entered '16 Aug 2020 12:03'	System	16 Aug 2020 17:03:17
	System	16 Aug 2020 17:03:17

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 4'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ecb9bc4f-9db6-48d5-a966-f6ff9ef2bf87'	System	18 Aug 2020 05:03:32
User entered 'None (1)'	System	18 Aug 2020 05:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:18', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ecb9bc4f-9db6-48d5-a966-f6ff9ef2bf87'	System	18 Aug 2020 05:03:32
User entered 'No (N)'	System	18 Aug 2020 05:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:20', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ecb9bc4f-9db6-48d5-a966-f6ff9ef2bf87'	System	18 Aug 2020 05:03:32
User entered 'No (N)'	System	18 Aug 2020 05:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:22', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ecb9bc4f-9db6-48d5-a966-f6ff9ef2bf87' User entered 'None (1)'	System	18 Aug 2020 05:03:32
	System	18 Aug 2020 05:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:26', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'ecb9bc4f-9db6-48d5-a966-f6ff9ef2bf87' User entered '18 Aug 2020 00:03'	System	18 Aug 2020 05:03:32
	System	18 Aug 2020 05:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 5'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:46', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '636550c0-7ddc-4a02-b86e-b67b841010c9' User entered 'None (1)'	System	19 Aug 2020 05:01:16
	System	19 Aug 2020 05:01:16

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '636550c0-7ddc-4a02-b86e-b67b841010c9' User entered 'No (N)'	System	19 Aug 2020 05:01:16
	System	19 Aug 2020 05:01:16

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:54', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '636550c0-7ddc-4a02-b86e-b67b841010c9' User entered 'No (N)'	System	19 Aug 2020 05:01:16
	System	19 Aug 2020 05:01:16

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:00:58', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '636550c0-7ddc-4a02-b86e-b67b841010c9' User entered 'None (1)'	System	19 Aug 2020 05:01:16
	System	19 Aug 2020 05:01:16

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '636550c0-7ddc-4a02-b86e-b67b841010c9' User entered '19 Aug 2020 00:01'	System	19 Aug 2020 05:01:16
	System	19 Aug 2020 05:01:16

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 6'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:34:56', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '84f60b6c-b5f0-459f-a4d3-f977ad503bd8'	System	20 Aug 2020 06:35:11
User entered 'None (1)'	System	20 Aug 2020 06:35:11

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '84f60b6c-b5f0-459f-a4d3-f977ad503bd8'	System	20 Aug 2020 06:35:11
User entered 'No (N)'	System	20 Aug 2020 06:35:11

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:05', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '84f60b6c-b5f0-459f-a4d3-f977ad503bd8'	System	20 Aug 2020 06:35:11
User entered 'No (N)'	System	20 Aug 2020 06:35:11

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:07', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '84f60b6c-b5f0-459f-a4d3-f977ad503bd8' User entered 'None (1)'	System	20 Aug 2020 06:35:11
	System	20 Aug 2020 06:35:11

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:09', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '84f60b6c-b5f0-459f-a4d3-f977ad503bd8'	System	20 Aug 2020 06:35:11
User entered '20 Aug 2020 01:35'	System	20 Aug 2020 06:35:11

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 7'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:39', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1e902a65-eb22-461d-8179-a1345f141251'	System	21 Aug 2020 01:34:48
User entered 'None (1)'	System	21 Aug 2020 01:34:48

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:41', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1e902a65-eb22-461d-8179-a1345f141251'	System	21 Aug 2020 01:34:48
User entered 'No (N)'	System	21 Aug 2020 01:34:48

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:43', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1e902a65-eb22-461d-8179-a1345f141251'	System	21 Aug 2020 01:34:48
User entered 'No (N)'	System	21 Aug 2020 01:34:48

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:45', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1e902a65-eb22-461d-8179-a1345f141251' User entered 'None (1)'	System	21 Aug 2020 01:34:48
	System	21 Aug 2020 01:34:48

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:46', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1e902a65-eb22-461d-8179-a1345f141251' User entered '20 Aug 2020 20:34'	System	21 Aug 2020 01:34:48
	System	21 Aug 2020 01:34:48

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:38', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:46', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:52', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:35:57', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:36:02', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:36:07', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'None (0)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:36:33', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered 'No (N)'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T15:36:37', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '941452c0-e9c3-4cd9-907f-a08c0e976e14' User entered '14 Aug 2020 15:36'	System	14 Aug 2020 20:36:40
	System	14 Aug 2020 20:36:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 15:22'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 17:52'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:56', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:00:59', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:03', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:05', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:07', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:09', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'None (0)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:18', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered 'No (N)'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-14T19:01:22', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '27a2504b-f351-4a92-8b13-b28fd6e27fd9' User entered '14 Aug 2020 19:01'	System	15 Aug 2020 00:01:25
	System	15 Aug 2020 00:01:25

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '14 Aug 2020 18:47'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 2'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:34', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:36', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:38', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:41', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:43', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:45', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'None (0)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered 'No (N)'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-15T12:10:53', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0425f093-be72-48d2-87fa-59a666ded51d' User entered '15 Aug 2020 12:10'	System	15 Aug 2020 17:10:54
	System	15 Aug 2020 17:10:54

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 3'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:19', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:21', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:22', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:24', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88' User entered 'None (0)'	System	16 Aug 2020 17:03:32
	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:28', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88'	System	16 Aug 2020 17:03:32
User entered 'No (N)'	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-16T12:03:30', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd9459eed-e1c4-4654-b87c-ee2e61e07e88'	System	16 Aug 2020 17:03:32
User entered '16 Aug 2020 12:03'	System	16 Aug 2020 17:03:32

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 4'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:36', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181'	System	18 Aug 2020 05:04:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:40', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'None (0)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:54', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'None (0)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:56', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'None (0)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:58', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'None (0)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:03:59', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'None (0)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:04:02', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered 'No (N)'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-18T00:04:06', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '963be9b4-c62e-4dff-ac77-43fab50c2181' User entered '18 Aug 2020 00:04'	System	18 Aug 2020 05:04:09
	System	18 Aug 2020 05:04:09

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 5'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:03', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered 'None (0)'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:05', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered 'None (0)'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:07', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered 'None (0)'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:09', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702' User entered 'None (0)'	System	19 Aug 2020 05:01:23
	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:10', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered 'None (0)'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:12', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702' User entered 'None (0)'	System	19 Aug 2020 05:01:23
	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered 'No (N)'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-19T00:01:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'dc6bafb7-a826-40b3-829f-cc1f1cd9d702'	System	19 Aug 2020 05:01:23
User entered '19 Aug 2020 00:01'	System	19 Aug 2020 05:01:23

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 6'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:19', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:20', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:22', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:23', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'None (0)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:26', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered 'No (N)'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T01:35:29', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'bcbbb58a-bb87-415a-a7c8-7d3a1553f08e' User entered '20 Aug 2020 01:35'	System	20 Aug 2020 06:35:31
	System	20 Aug 2020 06:35:31

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 7'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:49', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:51', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:53', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:54', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:55', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered 'None (0)'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:56', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3'	System	21 Aug 2020 01:35:02
User entered 'No (N)'	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-08-20T20:34:58', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '787bdc46-ecff-499b-9c40-3e0797c5f4d3' User entered '20 Aug 2020 20:34'	System	21 Aug 2020 01:35:02
	System	21 Aug 2020 01:35:02

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:04:40

US3212182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Aug 2020 21:11:33

US3212182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '21 Aug 2020'	Heather Leary (b) (4)	21 Aug 2020 21:11:33

US3212182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	21 Aug 2020 21:11:33

US3212182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Heather Leary (b) (4)	21 Aug 2020 21:11:33

US3212182

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Aug 2020 21:11:48

US3212182

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	21 Aug 2020 21:11:48

US3212182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:21:44

US3212182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '29 Aug 2020'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:21:44

US3212182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:21:44

US3212182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:21:44

US3212182

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:21:50

US3212182

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	31 Aug 2020 17:21:50

US3212182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Sep 2020 16:29:24

US3212182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '04 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:32:11
User entered '4 Sep 2020'	Heather Leary (b) (4)	05 Sep 2020 16:29:24

US3212182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	05 Sep 2020 16:29:24

US3212182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Heather Leary (b) (4)	05 Sep 2020 16:29:24

US3212182

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:06:32

US3212182

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	11 Sep 2020 19:06:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:06:42

US3212182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 19:06:42

US3212182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	11 Sep 2020 19:06:42

US3212182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT2'	System	11 Sep 2020 19:06:42

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11:09' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '11 Sep 2020 11:09'	System	11 Sep 2020 19:14:20
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '97.3' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '66' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	11 Sep 2020 19:14:20
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '16' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	11 Sep 2020 19:14:20
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '123' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	11 Sep 2020 19:14:20
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '75' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Sep 2020 19:14:20
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	11 Sep 2020 19:14:20
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:07:06

US3212182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:07:41

US3212182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 19:07:41

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Urine (URINE)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 14:34:00
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Submitted to IQVIA' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 19:09:05
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	11 Sep 2020 19:08:05
User entered 'Positive (POSITIVE)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:05

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Pregnancy (PREGNANCY)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:32

US3212182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:43

US3212182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:43

US3212182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13:48'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:43

US3212182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '11 Sep 2020 13:48'	System	11 Sep 2020 19:08:43

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:11:25

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13:43'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered empty.	System	11 Sep 2020 19:08:57

US3212182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:19:44
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Sep 2020 19:09:10

US3212182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '1'	System	21 Sep 2020 14:19:44
User entered empty.	System	11 Sep 2020 19:09:10

US3212182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:19:56

US3212182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Sep 2020'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:19:56

US3212182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:19:56

US3212182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:19:56

US3212182

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:20:01

US3212182

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	21 Sep 2020 14:20:01

US3212182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 13:45:58

US3212182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 13:45:58

US3212182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 13:45:58

US3212182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	28 Sep 2020 13:45:58

US3212182

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 13:46:02

US3212182

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	28 Sep 2020 13:46:02

US3212182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	07 Oct 2020 13:43:19

US3212182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	19 Jan 2021 22:43:02
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	07 Oct 2020 13:43:19

US3212182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	07 Oct 2020 13:43:19

US3212182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	07 Oct 2020 13:43:19

US3212182

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	07 Oct 2020 13:43:30

US3212182

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	07 Oct 2020 13:43:30

US3212182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:32

US3212182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:36:46
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:32

US3212182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:32

US3212182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT3'	System	09 Oct 2020 18:30:32

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:36:54
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '12:23'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '09 Oct 2020 12:23'	System	14 Dec 2020 17:36:54
User entered '9 Oct 2020 12:23'	System	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '98.5' F	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '67'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '106'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '62'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	09 Oct 2020 18:32:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:36:59
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:46

US3212182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:33:03

US3212182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:37:06
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:33:03

US3212182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13:16'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:33:03

US3212182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '09 Oct 2020 13:16'	System	14 Dec 2020 17:37:06
User entered '9 Oct 2020 13:16'	System	09 Oct 2020 18:33:03

US3212182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Oct 2020 18:30:20

US3212182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	09 Oct 2020 18:30:20

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 64'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:03', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f' User entered 'Yes (Y)'	System	16 Oct 2020 16:54:40
	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:08', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f' User entered 'No (N)'	System	16 Oct 2020 16:54:40
	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f'	System	16 Oct 2020 16:54:40
User entered 'No (N)'	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:19', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f'	System	16 Oct 2020 16:54:40
User entered 'Yes (Y)'	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:25', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f'	System	16 Oct 2020 16:54:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-16T11:54:29', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4b60e9e7-6101-4197-a346-5a6fdb64138f' User entered '16 Oct 2020 11:54:29'	System	16 Oct 2020 16:54:40
	System	16 Oct 2020 16:54:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 71'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-25T11:59:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a5d51d2a-9ad3-4b5a-ad6a-45ed475edb7c' User entered 'No (N)'	System	25 Oct 2020 17:05:52
	System	25 Oct 2020 17:05:52

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-25T12:05:46', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a5d51d2a-9ad3-4b5a-ad6a-45ed475edb7c'	System	25 Oct 2020 17:05:52
User entered 'No (N)'	System	25 Oct 2020 17:05:52

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-25T12:05:50', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'a5d51d2a-9ad3-4b5a-ad6a-45ed475edb7c' User entered '25 Oct 2020 12:05:50'	System	25 Oct 2020 17:05:52
	System	25 Oct 2020 17:05:52

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 78'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:27', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d'	System	28 Oct 2020 20:57:05
User entered 'Yes (Y)'	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:30', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d'	System	28 Oct 2020 20:57:05
User entered 'No (N)'	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:32', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d'	System	28 Oct 2020 20:57:05
User entered 'No (N)'	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:38', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d'	System	28 Oct 2020 20:57:05
User entered 'Yes (Y)'	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:42', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d'	System	28 Oct 2020 20:57:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-10-28T15:56:44', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '404a7681-3931-4ce6-903b-52e6605ff51d' User entered '28 Oct 2020 15:56:44'	System	28 Oct 2020 20:57:05
	System	28 Oct 2020 20:57:05

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 92'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-15T11:59:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd268ce9d-1231-4106-94f3-ced0863683f4' User entered 'No (N)'	System	15 Nov 2020 17:59:35
	System	15 Nov 2020 17:59:35

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-15T11:59:29', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd268ce9d-1231-4106-94f3-ced0863683f4'	System	15 Nov 2020 17:59:35
User entered 'No (N)'	System	15 Nov 2020 17:59:35

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-15T11:59:31', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd268ce9d-1231-4106-94f3-ced0863683f4' User entered '15 Nov 2020 11:59:31'	System	15 Nov 2020 17:59:35
	System	15 Nov 2020 17:59:35

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:12:20
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19
Data entry locked.	System	14 Aug 2020 20:04:40
User entered 'Day 99'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 20:04:40

US3212182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:49:19
Data entry locked.	System	14 Aug 2020 20:04:40
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 20:04:40

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-25T18:03:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'feff9083-b0f9-4859-ac34-e95b1539a828'	System	26 Nov 2020 00:03:19
User entered 'No (N)'	System	26 Nov 2020 00:03:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-25T18:03:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'feff9083-b0f9-4859-ac34-e95b1539a828'	System	26 Nov 2020 00:03:19
User entered 'No (N)'	System	26 Nov 2020 00:03:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-11-25T18:03:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'feff9083-b0f9-4859-ac34-e95b1539a828' User entered '25 Nov 2020 18:03:17'	System	26 Nov 2020 00:03:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-10T11:59:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6466fc1-36a4-4307-8c1b-6bc888753a06'	System	10 Dec 2020 17:59:26
User entered 'No (N)'	System	10 Dec 2020 17:59:26

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-10T11:59:19', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6466fc1-36a4-4307-8c1b-6bc888753a06'	System	10 Dec 2020 17:59:26
User entered 'No (N)'	System	10 Dec 2020 17:59:26

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-10T11:59:21', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'f6466fc1-36a4-4307-8c1b-6bc888753a06' User entered '10 Dec 2020 11:59:21'	System	10 Dec 2020 17:59:26
	System	10 Dec 2020 17:59:26

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-17T12:08:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3beec714-a9f9-42c3-beee-5e85770e4025'	System	29 Dec 2020 18:01:44
User entered 'No (N)'	System	29 Dec 2020 18:01:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-17T12:08:02', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3beec714-a9f9-42c3-beee-5e85770e4025' User entered 'No (N)'	System	29 Dec 2020 18:01:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-17T12:08:04', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3beec714-a9f9-42c3-beee-5e85770e4025' User entered '17 Dec 2020 12:08:04'	System	29 Dec 2020 18:01:44
	System	29 Dec 2020 18:01:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:01:48', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890'	System	29 Dec 2020 18:02:24
User entered 'Yes (Y)'	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:01:55', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890'	System	29 Dec 2020 18:02:24
User entered 'No (N)'	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:01:58', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890' User entered 'No (N)'	System	29 Dec 2020 18:02:24
	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:02:05', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890'	System	29 Dec 2020 18:02:24
User entered 'Yes (Y)'	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:02:10', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890'	System	29 Dec 2020 18:02:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2020-12-29T12:02:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1f422d69-ba15-4fa9-bc05-bdd938996890' User entered '29 Dec 2020 12:02:13'	System	29 Dec 2020 18:02:24
	System	29 Dec 2020 18:02:24

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-14T12:11:08', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3ecda5ac-9b32-4137-800b-b6f0336f6791'	System	14 Jan 2021 18:11:15
User entered 'No (N)'	System	14 Jan 2021 18:11:15

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-14T12:11:10', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3ecda5ac-9b32-4137-800b-b6f0336f6791'	System	14 Jan 2021 18:11:15
User entered 'No (N)'	System	14 Jan 2021 18:11:15

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-14T12:11:12', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '3ecda5ac-9b32-4137-800b-b6f0336f6791' User entered '14 Jan 2021 12:11:12'	System	14 Jan 2021 18:11:15
	System	14 Jan 2021 18:11:15

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-21T11:59:13', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '94e7fa59-4b12-4492-8787-1c2eba21fa8e' User entered 'No (N)'	System	21 Jan 2021 17:59:20
	System	21 Jan 2021 17:59:20

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-21T11:59:15', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '94e7fa59-4b12-4492-8787-1c2eba21fa8e' User entered 'No (N)'	System	21 Jan 2021 17:59:20

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-21T11:59:17', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '94e7fa59-4b12-4492-8787-1c2eba21fa8e' User entered '21 Jan 2021 11:59:17'	System	21 Jan 2021 17:59:20
	System	21 Jan 2021 17:59:20

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-24T01:18:41', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '00a34092-e431-49e9-93c1-940a548c6973'	System	24 Jan 2021 07:18:47
User entered 'No (N)'	System	24 Jan 2021 07:18:47

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-24T01:18:43', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '00a34092-e431-49e9-93c1-940a548c6973'	System	24 Jan 2021 07:18:47
User entered 'No (N)'	System	24 Jan 2021 07:18:47

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-24T01:18:45', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '00a34092-e431-49e9-93c1-940a548c6973' User entered '24 Jan 2021 01:18:45'	System	24 Jan 2021 07:18:47
	System	24 Jan 2021 07:18:47

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:58:32', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered 'Yes (Y)'	System	31 Jan 2021 21:59:22
	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:58:34', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered 'Yes (Y)'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:58:37', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:58:39', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered 'Yes (Y)'	System	31 Jan 2021 21:59:22
	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '0'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '0'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered '1'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '0'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '0'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:01', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '0'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:04', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:08', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered 'Yes (Y)'	System	31 Jan 2021 21:59:22
	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:09', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871'	System	31 Jan 2021 21:59:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-01-31T15:59:12', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '0c849b57-4bd1-40a1-8adc-52d0bb0ee871' User entered '31 Jan 2021 15:59:12'	System	31 Jan 2021 21:59:22
	System	31 Jan 2021 21:59:22

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:38', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered 'Yes (Y)'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:44', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered 'No (N)'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:47', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered 'No (N)'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:54', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered 'Yes (Y)'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:57', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-02-11T21:38:59', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'd5d71fd3-dafb-40f6-80d2-655e32b6f155'	System	12 Feb 2021 03:39:12
User entered '11 Feb 2021 21:38:59'	System	12 Feb 2021 03:39:12

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-04T12:43:40', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4358c125-3043-4c03-9173-15c2afb4b639'	System	04 Mar 2021 18:43:49
User entered 'No (N)'	System	04 Mar 2021 18:43:49

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-04T12:43:42', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4358c125-3043-4c03-9173-15c2afb4b639'	System	04 Mar 2021 18:43:49
User entered 'No (N)'	System	04 Mar 2021 18:43:49

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-04T12:43:44', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '4358c125-3043-4c03-9173-15c2afb4b639' User entered '04 Mar 2021 12:43:44'	System	04 Mar 2021 18:43:49
	System	04 Mar 2021 18:43:49

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-18T09:12:37', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '5d48974b-f463-48fd-bfd9-d3787a6f4956'	System	18 Mar 2021 14:12:43
User entered 'No (N)'	System	18 Mar 2021 14:12:43

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-18T09:12:39', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '5d48974b-f463-48fd-bfd9-d3787a6f4956'	System	18 Mar 2021 14:12:43
User entered 'No (N)'	System	18 Mar 2021 14:12:43

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-18T09:12:41', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '5d48974b-f463-48fd-bfd9-d3787a6f4956' User entered '18 Mar 2021 09:12:41'	System	18 Mar 2021 14:12:43
	System	18 Mar 2021 14:12:43

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-08T09:58:37-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '22a6f78c-7568-4083-b061-9ea0d3892803'	System	08 Apr 2021 14:58:44
User entered 'No (N)'	System	08 Apr 2021 14:58:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-08T09:58:39-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '22a6f78c-7568-4083-b061-9ea0d3892803'	System	08 Apr 2021 14:58:44
User entered 'No (N)'	System	08 Apr 2021 14:58:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-08T09:58:41-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '22a6f78c-7568-4083-b061-9ea0d3892803'	System	08 Apr 2021 14:58:44
User entered '08 Apr 2021 09:58:41'	System	08 Apr 2021 14:58:44

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-14T18:06:32-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '65f3902f-be28-417c-b8aa-f2bdc39c34c8'	System	14 Apr 2021 23:06:39
User entered 'No (N)'	System	14 Apr 2021 23:06:39

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-14T18:06:33-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '65f3902f-be28-417c-b8aa-f2bdc39c34c8'	System	14 Apr 2021 23:06:39
User entered 'No (N)'	System	14 Apr 2021 23:06:39

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-14T18:06:35-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '65f3902f-be28-417c-b8aa-f2bdc39c34c8'	System	14 Apr 2021 23:06:39
User entered '14 Apr 2021 18:06:35'	System	14 Apr 2021 23:06:39

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-18T02:36:58-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1d528276-15d2-4b5a-995b-e4916aa9a276'	System	18 Apr 2021 07:37:04
User entered 'No (N)'	System	18 Apr 2021 07:37:04

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-18T02:37:00-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1d528276-15d2-4b5a-995b-e4916aa9a276'	System	18 Apr 2021 07:37:04
User entered 'No (N)'	System	18 Apr 2021 07:37:04

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-18T02:37:01-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '1d528276-15d2-4b5a-995b-e4916aa9a276'	System	18 Apr 2021 07:37:04
User entered '18 Apr 2021 02:37:01'	System	18 Apr 2021 07:37:04

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-29T11:59:10-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '41b51622-de6d-4193-af27-64219837f934'	System	29 Apr 2021 16:59:17
User entered 'No (N)'	System	29 Apr 2021 16:59:17

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-29T11:59:11-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '41b51622-de6d-4193-af27-64219837f934'	System	29 Apr 2021 16:59:17
User entered 'No (N)'	System	29 Apr 2021 16:59:17

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-04-29T11:59:13-05:00', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: '41b51622-de6d-4193-af27-64219837f934'	System	29 Apr 2021 16:59:17
User entered '29 Apr 2021 11:59:13'	System	29 Apr 2021 16:59:17

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:49:19

US3212182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:49:19
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:49:19

US3212182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:11:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-04T12:43:49', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'fe68e719-a1bd-44c8-846a-1b45276f67af'	System	04 Mar 2021 18:43:54
User entered 'No (N)'	System	04 Mar 2021 18:43:54

US3212182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:11:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C87FF6F8-5FF8-4CD9-8F36-87429A531B00)', Time: '2021-03-04T12:43:51', User OID: 'PatientReportedOutcome (US3212182)', ODM File OID: 'fe68e719-a1bd-44c8-846a-1b45276f67af' User entered '04 Mar 2021 12:43:51'	System	04 Mar 2021 18:43:54
	System	04 Mar 2021 18:43:54

US3212182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 14:52:05

US3212182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '05 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:31:44
User entered '5 Nov 2020'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 14:52:05

US3212182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 14:52:05

US3212182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	06 Nov 2020 14:52:05

US3212182

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Nov 2020 14:52:11

US3212182

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	06 Nov 2020 14:52:11

US3212182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Dec 2020 17:13:47

US3212182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Dec 2020'	Laura Ngansop Djampou (b) (4)	15 Dec 2020 17:13:47

US3212182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	15 Dec 2020 17:13:47

US3212182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	15 Dec 2020 17:13:47

US3212182

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Dec 2020 17:13:52

US3212182

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	15 Dec 2020 17:13:52

US3212182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 15:11:01

US3212182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '08 Jan 2021'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 15:11:01

US3212182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 15:11:01

US3212182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Called for safety call, no answer, left voicemail'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 15:11:01

US3212182

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 15:11:08

US3212182

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	11 Jan 2021 15:11:08

US3212182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 18:23:21

US3212182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '10 Feb 2021'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 18:23:21

US3212182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 18:23:21

US3212182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	19 Feb 2021 18:23:21

US3212182

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 18:23:08

US3212182

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	19 Feb 2021 18:23:08

US3212182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:04:54

US3212182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:04:54

US3212182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:04:54

US3212182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT4'	System	19 Mar 2021 15:04:54

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '08:45'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '18 Mar 2021 08:45'	System	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '98.2' F	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '85'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '17'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '90'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '65'	Afifah Ayub (b) (4)	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	30 Mar 2021 16:14:59

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:05

US3212182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:05

US3212182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:19

US3212182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:19

US3212182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09:45'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:19

US3212182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '18 Mar 2021 09:45'	System	19 Mar 2021 15:05:19

US3212182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:05:30

US3212182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	19 Mar 2021 15:05:30

US3212182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:43
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	09 Apr 2021 14:47:36

US3212182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:43
User entered '08 Apr 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	09 Apr 2021 14:47:36

US3212182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	09 Apr 2021 14:47:36

US3212182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:43
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	09 Apr 2021 14:47:36

US3212182

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:43
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	09 Apr 2021 14:47:23

US3212182

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:47:23

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:51
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '1 Feb 2021'	Heather Leary (b) (4)	28 Apr 2021 20:29:40

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:51
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '14:22'	Heather Leary (b) (4)	28 Apr 2021 20:29:40

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:51
User entered '1 Feb 2021 14:22'	System	28 Apr 2021 20:29:40

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:51
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Safety Call (Safety Call)'	Heather Leary (b) (4)	28 Apr 2021 20:29:40

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:51
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	28 Apr 2021 20:29:40

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 1 (Day 1)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '28 Jan 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '18 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '0'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered missing code ND - Not Done.	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered '%'	System	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered missing code ND - Not Done.	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Moderate (Moderate)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'None (None)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'None (None)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'None (None)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Mild (Mild)'	Heather Leary (b) (4)	28 Apr 2021 20:34:58

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 2 (Day 2)'	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '29 Jan 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '19 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:12

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 3 (Day 3)'	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '30 Jan 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '20 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:21

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 4 (Day 4)'	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '31 Jan 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '21 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:35

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 5 (Day 5)'	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '01 Feb 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '22 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:46

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 6 (Day 6)'	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '02 Feb 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:36:59
User entered '23 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:35:57

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:35:57

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 7 (Day 7)'	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '03 Feb 2021'	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:37:44
User entered '0'	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:36:59

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 8 (Day 8)'	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '4 Feb 2021'	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:37:44

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

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Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:44

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 9 (Day 9)'	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '5 Feb 2021'	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:37:53

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Day 10 (Day 10)'	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '6 Feb 2021'	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'I'	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User entered empty.	System	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:32:58
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:38:10

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '28 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 05:09:31
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE is entered' (Site from System).	Heather Leary (b) (4)	28 Apr 2021 20:43:13
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	28 Apr 2021 20:42:27
User entered 'Yes (Y)'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered '28 Jan 2021'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered empty.	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'CVS MinuteClinic, 602 W Grand Pkwy S, Katy TX 77494 LumiraDX SARS-COV-2 AG Test'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	28 Apr 2021 20:42:27

US3212182

Folder: Covid-19 Assessment 01 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:25

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:33:07
User entered 'I'	System	28 Apr 2021 20:42:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:06:56

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:06:56

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:06:56

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User entered 'UNBLND_DECIDE'	System	19 Mar 2021 15:06:56

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Amendment 6 or later (Amendment 6 or later)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User entered empty.	System	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:11:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User entered empty.	System	19 Mar 2021 15:07:27

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:35

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:35

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:35

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User entered empty.	System	19 Mar 2021 15:07:35

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:52

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:25

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Mar 2021'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:52

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '09:40'	Laura Ngansop Djampou (b) (4)	19 Mar 2021 15:07:52

US3212182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:25

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:21:15
User entered '18 Mar 2021 09:40'	System	19 Mar 2021 15:07:52

US3212182

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:11:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:22
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)' reason for change: New Information	Afifah Ayub (b) (4)	12 Oct 2020 14:58:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 20:55:14

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Maternal complications of pregnancy NEC, PT: Morning sickness, LLT: Morning sickness - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:59:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:59:24
Data point term sent to Coder	System	12 Oct 2020 14:59:01
User entered 'morning sickness'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '13 Sep 2020'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User entered empty.	System	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:38:13
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 18:38:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:37:28
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:38:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Nov 2020 18:38:13
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:37:28
User entered '26 Oct 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 18:37:28
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User entered empty.	System	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the reason for dosing discontinuation in the Dosing Discontinuation eCRF. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:55:28
Query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the reason for dosing discontinuation in the Dosing Discontinuation eCRF. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 20:24:20
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 20:24:15
User opened query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the reason for dosing discontinuation in the Dosing Discontinuation eCRF. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 01:56:36
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:08:07
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:07:27
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	29 Oct 2020 15:37:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Subject came in for visit 2 and tested positive for Urine pregnancy test. She reports continued compliance with condoms used in conjunction with spermicide as per protocol. PI authorized Serum HCG testing from local labs. Vaccination has been withheld as per protocol. Pregnancy report sent to IQVIA within 24 hours. ePIP has been sent as well. She has agreed to remain in the study and be followed-up for safety.' (Site from System).	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 15:37:41
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	29 Oct 2020 15:36:33
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:37:55
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Afifah Ayub (b) (4) (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 17:56:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 17:56:28
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 18:38:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User entered '0'	System	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12
User entered '0'	System	12 Oct 2020 14:58:42

US3212182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:12

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Streptococcal infection, LLT: Streptococcal infection - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:37:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:37:36
Data point term sent to Coder	System	26 Oct 2020 15:46:54
User entered 'Group B streptococcal infection (GBS positive)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '15 Oct 2020'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User entered empty.	System	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 16:31:14
User entered 'Yes (Y)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 16:46:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Nov 2020 16:46:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 16:31:14
User entered '25 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 16:31:14
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User entered empty.	System	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:09:25
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Reagan Reed (b) (4)	18 Nov 2020 14:59:00
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	18 Nov 2020 14:58:55
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:51:16
User entered 'Not Applicable (NOT APPLICABLE)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'None (NONE)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 16:46:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User entered '0'	System	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13
User entered 'I'	System	26 Oct 2020 15:46:03

US3212182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4), (b) (6)	23 Nov 2020 20:03:22
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).		
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 18:39:23
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 10:39:59
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Maternal complications of pregnancy NEC, PT: Hyperemesis gravidarum, LLT: Hyperemesis gravidarum - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 18:24:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 18:24:27
Data point term sent to Coder	System	04 Nov 2020 18:23:49
User entered 'Hyperemesis gravidarum'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '26 Oct 2020'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:23:48

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:23:48

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'None (NONE)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '1'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:23:48
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:23:48

US3212182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:23:48

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4), (b) (6)	
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).		29 Mar 2021 09:22:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 16:25:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 16:25:40
Data point term sent to Coder	System	26 Mar 2021 16:08:12
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'PD acknowledged for missed illness visit ' (Site from DM).	Reagan Reed (b) (4)	26 Mar 2021 16:07:32
Coding entries removed.	Reagan Reed (b) (4)	26 Mar 2021 16:07:18
User entered 'Chronic COUGH' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:07:18
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:53:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 19:44:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 19:44:47
Data point term sent to Coder	System	12 Mar 2021 19:44:24
User entered 'Cough'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:46:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 19:46:02
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:46:02
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:43:28
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Jan 2021'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:45:23
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:04:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:45:23
User entered '15 Mar 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:04:56
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:45:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'None (NONE)'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:45:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:04:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:43:28
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 19:43:28

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 19:53:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 19:53:50
Data point term sent to Coder	System	12 Mar 2021 19:52:31
User entered 'Iron Deficiency Anemia'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '04 Mar 2021'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Mar 2021 19:51:51
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:51
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Mar 2021 19:51:33
User entered '10:30'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 19:51:51
User entered '04 Mar 2021 10:30'	System	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 13:41:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 13:41:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Reagan Reed (b) (4)	16 Mar 2021 13:41:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:51:33
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 13:41:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 13:41:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	16 Mar 2021 13:41:23
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:51:33
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 13:41:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 13:41:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	16 Mar 2021 13:41:23
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:51:33
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 13:41:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 13:41:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	16 Mar 2021 13:41:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 19:51:33
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	12 Mar 2021 19:51:33
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 19:51:33

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:34:51
User entered 'USA-US115-2021-mRNA-1273-P301000018'	System	29 Mar 2021 19:34:41
User entered 'New'	(b) (4), (b) (6)	29 Mar 2021 19:34:41

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 17:47:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 17:47:47
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:47:14
User entered 'COVID 19'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4), (b) (6)	30 Mar 2021 13:09:25
User closed query 'Per CDM: Please verify that Indication is COVID-19. However Is this event a confirmed diagnosis of Symptomatic Covid-19? is provided as NO. Please review and update accordingly. Else clarify.' (Site from DM). Query 'Per CDM: Please verify that Indication is COVID-19. However Is this event a confirmed diagnosis of Symptomatic Covid-19? is provided as NO. Please review and update accordingly. Else clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	26 Mar 2021 16:08:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:08:17
User opened query 'Per CDM: Please verify that Indication is COVID-19. However Is this event a confirmed diagnosis of Symptomatic Covid-19? is provided as NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:05:22
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '28 Jan 2021'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:48:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:47:34
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	22 Mar 2021 17:48:24
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 17:48:24
User entered '06 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:48:24
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Mar 2021 17:47:34
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	22 Mar 2021 17:46:50
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Mar 2021 17:46:50
User entered empty.	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'None (NONE)'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
Signature has been broken.	Heather Leary (b) (4)	28 Apr 2021 20:51:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:51:00
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '1'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
Signature has been broken.	Heather Leary (b) (4)	28 Apr 2021 20:51:00
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:51:00
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou	22 Mar 2021 17:46:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	30 Apr 2021 18:13:28
Signature has been broken.	Heather Leary (b) (4)	28 Apr 2021 20:46:05
	(b) (4)	
User entered 'Subject was scheduled for illness visit on 02FEB2021. She did not arrive for the appointment and was contacted on 2FEB2021 @ 1036, 3FEB2021 @ 1720, and 4FEB2021 @ 1343 to schedule illness visit, no reply. Action taken for missed illness visit - Subject was reached today 12Mar2021 for missed eduary and re-educated/ retrained to comply with study visits. Subject verbalized understanding. She did test positive for COVID19 on 28JAN with an outside study test and tested negative on 06FEB. Because subject was not compliant in attending illness visit, the visit was not performed and illness visit folder will remain empty.' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Apr 2021 20:46:05
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	22 Mar 2021 17:46:50

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 17:46:50

US3212182

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 17:46:50

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 15:24:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 15:24:26
Data point term sent to Coder	System	26 Mar 2021 15:23:54
User entered 'Gastroenteritis'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User entered empty.	System	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User entered empty.	System	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Reagan Reed (b) (4)	30 Mar 2021 13:27:52
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:09:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:09:07
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:09:07
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:23:31
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:09:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:09:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:09:07
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:23:31
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:09:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:09:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:09:07
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:23:31
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:09:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:09:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Mar 2021 16:09:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 15:23:31
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:23:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'conmed added' (Site from DM).	Jagruti Patel (b) (4) (b) (4)	05 Apr 2021 17:58:54
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:39:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

US3212182

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User entered '0'	System	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17
User entered 'I'	System	26 Mar 2021 15:23:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:11:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:27:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:11:25

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:22
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Per DM CLR: Per Diary Dose 1 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 21:38:52
Query 'Per DM CLR: Per Diary Dose 1 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'NO MEDICATION TAKEN' (Site from DM).	Heather Leary (b) (4) (b) (4)	25 Jan 2021 16:33:36
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:36:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 18:46:56

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
	(b) (4), (b) (6)	28 Oct 2020 19:34:53
User closed query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly. Please review Diary Dose 1 - Day 4 for clarity.' (Site from CRA).	Heather Leary (b) (4)	26 Oct 2020 16:36:21
Query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly. Please review Diary Dose 1 - Day 4 for clarity.' answered with 'Subject indicated "Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity" but did not mark "yes" to "Was medication taken today for fever or pain?".' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:55:56
User opened query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly. Please review Diary Dose 1 - Day 4 for clarity.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:55:21
User closed query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly.' (Site from CRA).	Heather Leary (b) (4)	16 Sep 2020 19:42:51
Query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly.' answered with 'ediary shows no medication was taken' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 22:57:43
User opened query 'Per the eDiary the subject took over the counter medication for headache on 18Aug20. Please confirm the medication that was taken and update the Con Med log accordingly.' (Site from CRA).		

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:21:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:21:36
Data point term sent to Coder	System	14 Aug 2020 18:48:28
User entered 'ALBUTEROL'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 18:47:32

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'ASTHMA RESCUE'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '90'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'ug (ug)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 21:39:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Afifah Ayub (b) (4)	15 Aug 2020 18:48:07
answered with 'Subject is currently on the medication.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:04:40
User entered 'UN UNK 2002'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:32
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:47:32

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:47:32

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 18:47:32

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:52:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:52:28
Data point term sent to Coder	System	12 Oct 2020 14:57:58
User entered 'Prenatal vitamin'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 09:54:46
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	30 Mar 2021 13:07:34
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	30 Mar 2021 13:07:09
	(b) (4)	
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:15:19
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'pregnancy'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '1'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'tablet (TABLET)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '14 Sep 2020'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	12 Oct 2020 14:57:42
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 14:57:42

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 14:57:42

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 14:57:42

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: BETA-LACTAMASE SENSITIVE PENICILLINS, PRODUCT: PHENOXYMETHYLPENICILLIN POTASSIUM, PRODUCTSYNONYM: PENICILLIN VK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 16:23:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 16:23:16
Data point term sent to Coder	System	26 Oct 2020 15:47:55
User entered 'Penicillin VK'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Group B Streptococcal Infection (GBS positive)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '250'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mg (mg)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'four times daily (QID)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (ORAL)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '21 Oct 2020'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 16:29:19
User entered 'Yes (Y)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '25 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 16:29:19
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Reagan Reed (b) (4)	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User entered '4'	System	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User entered '1'	System	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:03
User entered '804 (804)'	System	26 Oct 2020 15:47:17

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:47:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:47:22
Data point term sent to Coder	System	05 Nov 2020 16:31:09
User entered 'influenza vaccination'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'immunization'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0.5'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mL (mL)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'once (ONCE)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Intramuscular (INTRAMUSCULAR)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '16 Oct 2020'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '16 Oct 2020'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User entered empty.	System	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User entered empty.	System	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:07
User entered empty.	System	05 Nov 2020 16:30:43

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: OTHER COUGH SUPPRESSANTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:35:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:35:00
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:16:56
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	29 Mar 2021 14:03:18
Data point term sent to Coder Coding entries removed.	System	29 Mar 2021 13:56:36
	Reagan Reed (b) (4)	29 Mar 2021 13:55:49
User entered 'unknown COUGH DROPS' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Mar 2021 13:55:49
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 03:10:28

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: OTHER COUGH SUPPRESSANTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 08:11:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 08:11:39
Data point term sent to Coder	System	16 Mar 2021 19:46:30
User entered 'Cough Drops'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'cough'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'tablet (TABLET)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Jan 2021'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:02:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '12 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:02:38
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User entered empty.	System	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User entered empty.	System	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:15
User entered empty.	System	16 Mar 2021 19:46:13

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: CHILDREN'S DIMETAPP COLD & COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:54:56
Data point term sent to Coder	System	16 Mar 2021 19:47:30
User entered 'Children's Dimetapp'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'cough'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '20'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mL (mL)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '18 Jan 2021'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:02:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '12 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Mar 2021 15:02:58
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User entered empty.	System	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User entered empty.	System	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:20
User entered empty.	System	16 Mar 2021 19:46:44

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 20:04:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 20:04:54
Data point term sent to Coder	System	16 Mar 2021 19:48:34
Data point term sent to Coder	System	16 Mar 2021 19:47:30
User entered 'Ferrous Sulfate'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 19:47:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 19:47:52
User entered 'anemia' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Mar 2021 19:47:52
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 19:47:15
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '10'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'mg (mg)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '05 Mar 2021'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '0'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Mar 2021 19:47:15
	(b) (4)	

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:47:15

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:47:15

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 19:47:15

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:48:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:48:38
Data point term sent to Coder	System	05 Apr 2021 17:59:32
User entered 'Zofran'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'No (N)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'Gastroenteritis'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered '4'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'mg (mg)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered empty.	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'once (ONCE)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered empty.	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered empty.	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered '23 Mar 2021'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered '0'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'No (N)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered '23 Mar 2021'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:52:52
User entered 'No (N)'	Jagruti Patel (b) (4)	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User entered empty.	System	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User entered empty.	System	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:11:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:33:30
User entered empty.	System	05 Apr 2021 17:58:40

US3212182

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:11:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:47:48
	(b) (4)	

US3212182

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:25

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	29 Oct 2020 15:36:33

US3212182

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:25

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User closed query 'Per CDM: Please mention the reason with AE logline number in Adverse event page in which the reason was recorded Instead of AE term. Thankyou.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 15:57:55
Query 'Per CDM: Please mention the reason with AE logline number in Adverse event page in which the reason was recorded Instead of AE term. Thankyou.' answered with 'reason for discontinuation is noted here as pregnancy. no further action needed. ' (Site from DM).	Reagan Reed (b) (4)	17 Dec 2020 17:42:09
User opened query 'Per CDM: Please mention the reason with AE logline number in Adverse event page in which the reason was recorded Instead of AE term. Thankyou.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:57:24
User entered 'Pregnancy (PREGNANCY)'	Afifah Ayub (b) (4)	29 Oct 2020 15:36:33

US3212182

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:17
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered empty.	Afifah Ayub (b) (4)	29 Oct 2020 15:36:33

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:15
User entered 'USA-US115-2021-MRNA-1273-P301000018'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'Vicki'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'Miller'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'US'	System	29 Mar 2021 19:35:29

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:35:29

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:15
User entered 'USA-US115-2021-MRNA-1273-P301000018'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'No (N)'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'Vicki'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 19:35:19
User entered 'Miller'	System	29 Mar 2021 19:34:41

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'US'	System	29 Mar 2021 19:35:29

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:35:29

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:11:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered '29/Mar/2021 15:35'	System	29 Mar 2021 19:35:29

US3212182

Folder: SAE USA-US115-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:11:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:12:00
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 19:35:29