

US3432120 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:33:05

All time stamps listed in this document are displayed in GMT

US3432120

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Participant ID

US3432120

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

US3432120

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	12 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	SCRN
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US3432120

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
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	False

US3432120

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 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

US3432120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3432120

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Were any significant conditions reported?

Yes ☒
No ☐

US3432120

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432120

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Condition	ALLERGY TO LEVOFLOXACINE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3432120

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:13 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:13
Height (<i>xxx.x</i>)	158 cm
Weight (<i>xxx.x</i>)	55.2 kg
BMI (<i>xxx.x</i>)	22.11184 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3432120

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Date of assessment (dd MMM yyyy) 12 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

US3432120

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 12 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3432120

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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

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) 19 Feb 2021 01:29:47

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	12 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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US3432120

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103656

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) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Height	ND - Not Done
Weight	ND - Not Done

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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)	12 AUG 2020
Time of assessment (00:00-23:59)	17:13 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:13
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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)	12 AUG 2020
Time of assessment (00:00-23:59)	18:49 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 18:49
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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.

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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) _____

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 18:19 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 18:19

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

US3432120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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

Collection date (dd MMM yyyy)	12 AUG 2020
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Collection time (00:00-23:59)	17:31 (24 HR)
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Collection date and time (derived)	12 AUG 2020 17:31
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US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:35	12 AUG 2020 17:35
Nasopharyngeal Swab 2	No		

US3432120

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

98.2 °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

12 AUG 2020 18:49

PC Open Date & Time

12 AUG 2020 18:39

PC Close Date & Time

12 AUG 2020 21:09

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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 98.9 °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	12 AUG 2020 22:50
PC Open Date & Time	12 AUG 2020 22:04
PC Close Date & Time	13 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

98.8 °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

13 AUG 2020 13:50

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

99.5 °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

14 AUG 2020 12:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

99.4 °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

15 AUG 2020 17:08

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

98.8 °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 22:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

98.8 °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

17 AUG 2020 23:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

98.6 °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 23:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

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

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

12 AUG 2020 18:50

PC Open Date & Time

12 AUG 2020 18:39

PC Close Date & Time

12 AUG 2020 21:09

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

12 AUG 2020 22:51

PC Open Date & Time

12 AUG 2020 22:04

PC Close Date & Time

13 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

13 AUG 2020 13:51

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

14 AUG 2020 12:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

15 AUG 2020 17:08

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

16 AUG 2020 22:44

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

17 AUG 2020 23:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

18 AUG 2020 23:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 18:51
PC Open Date & Time	12 AUG 2020 18:39
PC Close Date & Time	12 AUG 2020 21:09

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 22:52
PC Open Date & Time	12 AUG 2020 22:04
PC Close Date & Time	13 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

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 ☒

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:52
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

48 of 2509

EAB) (1725)

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:33
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

50 of 2509

EAB) (1725)

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:08
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 2509

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:44
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

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 ☒

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

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
EAB) (1725)

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US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
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

US3432120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	08 SEP 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	VISIT2
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US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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)	8 SEP 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:56
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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)	8 SEP 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:30
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3432120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 8 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:50

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

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	11:22 (24 HR)
Collection date and time (derived)	8 SEP 2020 11:22

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	8 SEP 2020 11:26
Nasopharyngeal Swab 2	No		

US3432120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

08 SEP 2020 12:33

PC Open Date & Time

08 SEP 2020 12:10

PC Close Date & Time

08 SEP 2020 14:40

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

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	08 SEP 2020 22:38
PC Open Date & Time	08 SEP 2020 15:35
PC Close Date & Time	09 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

Yes ☒

No ☐

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

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 21:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

97.3 °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

10 SEP 2020 23:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

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

11 SEP 2020 15:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

98.4 °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

12 SEP 2020 23:22

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

98.3 °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 SEP 2020 06:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

98.3 °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 SEP 2020 07:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

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

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

08 SEP 2020 12:33

PC Open Date & Time

08 SEP 2020 12:10

PC Close Date & Time

08 SEP 2020 14:40

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

08 SEP 2020 22:38

PC Open Date & Time

08 SEP 2020 15:35

PC Close Date & Time

09 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

09 SEP 2020 21:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

10 SEP 2020 23:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

11 SEP 2020 15:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

12 SEP 2020 23:22

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

14 SEP 2020 06:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

15 SEP 2020 07:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:34
PC Open Date & Time	08 SEP 2020 12:10
PC Close Date & Time	08 SEP 2020 14:40

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 22:38
PC Open Date & Time	08 SEP 2020 15:35
PC Close Date & Time	09 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

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 ☒

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EAB) (1725)

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:54
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

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
EAB) (1725)

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US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

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 ☒

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:42
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 06:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

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)

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 07:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3432120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:30:23

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 01:30:23

Generated On: 09 Jun 2021 17:33:05

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)	15:51 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 15:51
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:30:23

Generated On: 09 Jun 2021 17:33:05

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.

US3432120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:30:23

Generated On: 09 Jun 2021 17:33:05

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 09 OCT 2020

Collection time (00:00-23:59) 15:57 (24 HR)

Collection date and time (derived) 09 OCT 2020 15:57

US3432120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:48

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 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	12 OCT 2020 11:25:29
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

19 OCT 2020 21:16:01

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

26 OCT 2020 15:49:15

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

12 NOV 2020 11:02:45

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

20 NOV 2020 18:20:40

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 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	30 NOV 2020 17:30:45
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

04 DEC 2020 00:11:23

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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	13 DEC 2020 17:13:30
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 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	20 DEC 2020 12:01:54
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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	28 DEC 2020 15:47:40
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 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	01 JAN 2021 08:51:33
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

10 JAN 2021 12:00:14

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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	18 JAN 2021 16:12:06
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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 JAN 2021 17:25:24

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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 JAN 2021 05:28:25

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

05 FEB 2021 00:03:10

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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 FEB 2021 16:08:07

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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

19 FEB 2021 06:49:54

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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	02 MAR 2021 12:01:08
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

Date and time of submission

05 MAR 2021 06:01:47

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

13 MAR 2021 10:37:04

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 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	21 MAR 2021 09:02:18
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☒

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 MAR 2021 18:04:33

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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	02 APR 2021 05:46:50
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

12 APR 2021 16:53:33

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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 APR 2021 05:43:23
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

23 APR 2021 07:31:30

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐ 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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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°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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 <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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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="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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐
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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3432120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:33:05

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		02 MAR 2021 12:00:58

US3432120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	12 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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US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:42 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 15:42
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3432120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

15:50 (24 HR)

Collection date and time (derived)

12 MAR 2021 15:50

US3432120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

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

US3432120

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Date of Contact	29 SEP 2020
Time of Contact	12:25
Date and Time of Contact (derived)	29 SEP 2020 12:25
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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 checked="" type="radio"/>
	Mild	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.7 C
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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 checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	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 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Date of Visit	29 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	29 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	01 OCT 2020
Day 5	Yes	02 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3432120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	SICKD1

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	12:27 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:27
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3432120

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 SEP 2020

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	19 JAN 2021
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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	UNBLND_DECIDE
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US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 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>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:28 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:28
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 19 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 15:40

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

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00-23:59)	14:32 (24 HR)
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Collection date and time (derived)	19 JAN 2021 14:32
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US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	14:38
Collection Date and Time (derived)	19 JAN 2021 14:38

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3432120

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	26 FEB 2021
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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	OLD29
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US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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)	26 FEB 2021
Time of assessment (00:00-23:59)	15:43 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:43
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	IR
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:52
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	IR
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3432120

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	26 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3432120

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 16:22 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 16:22

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

US3432120

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432120

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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

Visit date (dd MMM yyyy)	26 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	OLD57
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US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 15:40
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	068 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432120

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

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.

US3432120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

15:45 (24 HR)

Collection date and time (derived)

26 MAR 2021 15:45

US3432120

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID

Adverse event

LACK OF CONCENTRATION

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 AUG 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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EAB) (1725)

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

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 type="radio"/> Related <input checked="" 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)	

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID

Adverse event

HOARSE VOICE

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 AUG 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

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)	

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID

Adverse event

LACK OF CONCENTRATION

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)

8 SEP 2020

Start time (00:00-23:59)

12:05 (24 HR)

AE start date and time (derived)

8 SEP 2020 12:05

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 SEP 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 (3)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

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 type="radio"/> Related <input checked="" 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	SIMILAR TO PRIOR EPISODE
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 (4)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

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)

28 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)

30 SEP 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 (4)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID

Adverse event

FRACTURED LEFT DISTAL
RADIUS

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)

25 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 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 ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

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	True
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)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

AEID	USA-US078-2021-MRNA-1273-P30 1000012
Adverse event	SBO (SMALL BOWEL OBSTRUCTION)
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)	30 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 type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	02 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 25 Apr 2021 11:02:00

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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 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	True
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	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 25 Apr 2021 11:02:00

Generated On: 09 Jun 2021 17:33:05

PARTICIPANT REPORTS A
SMALL BOWEL OBSTRUCTION
THAT LEAD TO A HOSPITAL
STAY FROM 1/31/2021 TO
2/2/2021.

SMALL BOWEL XRAY: SHOWS
SMALL BOWEL OBSTRUCTION
CT ABDOMEN AND PELVIS:
SHOWS SMALL BOWEL
OBSTRUCTION WITH
TRANSITION POINT IN THE
RIGHT LOWER QUADRANT

REPORTS NP COVID TEST DONE
31JAN2021- NEGATIVE

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 (1)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)	UN UNK 2010	
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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 500

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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EAB) (1725)

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US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)	UN UNK 2010	
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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE
(REACTOGENICITY)

Dose per administration 1000

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) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 650

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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US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)		9 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FRACTURED ARM

Dose per administration 500

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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US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)		25 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FRACTURED ARM

Dose per administration 600

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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US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)		25 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration UNK

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNK

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 UNK

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)		31 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)		02 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"/>

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Name of Medication PAIN MEDICATION (UNKNOWN)

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration UNK

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

	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)	31 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)		02 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"/>

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 01:29:47

Generated On: 09 Jun 2021 17:33:05

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Apr 2021 11:02:01

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 DEC 2020	LEFT DISTAL RADIUS SURGERY - Adverse Event PUTTING PLATE IN		
01 FEB 2021	X-RAY SMALL BOWEL	Adverse Event	
31 JAN 2021	X RAY CHEST	Adverse Event	
31 JAN 2021	CT WITH CONTRAST OF ABDOMEN AND PELVIS	Adverse Event	
20 FEB 2021	MAMMOGRAM	Other	GENERAL HEALTH
09 APR 2021	BREAST BIOPSY	Diagnostic	

US3432120

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:33:05

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3432120

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:33:05

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 ☐

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/FEB/2021 07:23
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

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:44
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

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/MAR/2021 11:52
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

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 06:36
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

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 06:18
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

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 04 Apr 2021 20:35:10

Generated On: 09 Jun 2021 17:33:05

SAEID	USA-US078-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/MAR/2021 09:17
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

US3432120 (Prod: Brigham and Womens Hospital)

US3432120

Form: Participant Creation

Generated On: 09 Jun 2021 17:33:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US3432120'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:04:31

US3432120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:08

US3432120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:04:32

US3432120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[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 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:08

US3432120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'SCRN'	System	12 Aug 2020 22:45:08

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:04:33

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '46'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'YEARS'	System	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '46'	System	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Female (F)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'I'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:32

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'Aug 2020'	System	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '2020'	System	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Amendment 2 (2)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:24

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:04:32

US3432120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'I'	System	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:33:05

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:33:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:43:59

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 23:46:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 23:46:16
Data point term sent to Coder	System	12 Aug 2020 23:45:20
User entered 'Migraines'	Phoebe Cunningham	12 Aug 2020 23:44:24
	(b) (4)	

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'un UNK 1990'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'Jan 1990'	System	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '1990'	System	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	12 Aug 2020 23:44:24

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:18:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:18:15
Data point term sent to Coder	System	12 Aug 2020 23:45:20
User entered 'Allergy to Levofloxacin'	Phoebe Cunningham	12 Aug 2020 23:45:02
	(b) (4)	

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'un UNK 2017'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'Jan 2017'	System	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '2017'	System	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	12 Aug 2020 23:45:02

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '17:13'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '158' cm	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39
DataPoint set to visible.	System	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '55.2' kg	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39
DataPoint set to visible.	System	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
Amendment Manager: User entered '22.11184'	System	16 Sep 2020 23:54:28
User entered '22.1'	System	12 Aug 2020 23:48:39
DataPoint set to visible.	System	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'kg/m2'	System	12 Aug 2020 23:48:39
DataPoint set to visible.	System	12 Aug 2020 22:45:28

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered '36.9' C	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:27:57
Query 'Data is required. Please provide.' answered with 'No data is listed per (b) (6) request.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 20:07:28
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 20:07:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered '75'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'bpm'	System	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered '16'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'breaths/min'	System	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered '110'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 20:07:23
User entered '77'	Phoebe Cunningham	12 Aug 2020 23:48:39
	(b) (4)	

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	12 Aug 2020 23:48:39

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46

US3432120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46

US3432120

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:57

US3432120

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 10:49:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 15:52:02
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:22:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 23:09:31
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:48:57

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:33:05

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:13

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Urine (URINE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Negative (NEGATIVE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	12 Aug 2020 23:49:27

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'I'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:06

US3432120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:42

US3432120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:42

US3432120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	12 Aug 2020 22:45:42

US3432120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'VISIT1'	System	12 Aug 2020 22:45:42

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:34:13

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:02:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:02:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 21:34:13
User entered '103656' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:34:13

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:34:13

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

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)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:27

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

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)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:27

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:27

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:27

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:50:27

US3432120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'No (N)'	Bruce Bausk (b) (4)	02 Mar 2021 15:06:14
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:19:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:54:31

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '17:13'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '36.9' C	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '75'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'bpm'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '16'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'breaths/min'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '110'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '77'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
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)	17 Aug 2020 18:41:32
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vitals can be assessed 30 minutes following vaccination' (Site from System).	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:36
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).		12 Aug 2020 23:52:12
User entered '18:49'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '12 Aug 2020 18:49'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '36.8' C	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '65'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'bpm'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '15'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'breaths/min'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '122'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '78'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	12 Aug 2020 23:52:12

US3432120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:43

US3432120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:43

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:30:09
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'Although this goes against EDC guidelines, we are updating this.' (Site from DM).	Jun Bai Park Chang (b) (4)	22 Oct 2020 16:33:01
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	22 Oct 2020 16:32:57
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:34:02
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty; reason for change Per Query Resolution	Jun Bai Park Chang	22 Oct 2020 16:32:57
User entered '12 Aug 2020'	(b) (4)	
	Phoebe Cunningham	12 Aug 2020 23:52:59
	(b) (4)	

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty; reason for change Per Query Resolution	Jun Bai Park Chang (b) (4)	22 Oct 2020 16:32:57
User entered 'Urine (URINE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty; reason for change Per Query Resolution	Jun Bai Park Chang (b) (4)	22 Oct 2020 16:32:57
User entered 'Negative (NEGATIVE)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per CDM : Response is required for this field. Kindly enter as Yes/No' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:25:15
Query 'Per CDM : Response is required for this field. Kindly enter as Yes/No' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	05 Nov 2020 21:01:06
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	05 Nov 2020 21:00:59
User opened query 'Per CDM : Response is required for this field. Kindly enter as Yes/No' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:30:55
User entered empty; reason for change Per Query Resolution	Jun Bai Park Chang (b) (4)	22 Oct 2020 16:32:57
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered empty.	System	12 Aug 2020 23:52:59

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

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)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '18:19'	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '12 Aug 2020 18:19'	System	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4)	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'ONCE'	System	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 22:46:16

US3432120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:53:30

US3432120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:53:30

US3432120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '17:31'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:53:30

US3432120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '12 Aug 2020 17:31'	System	12 Aug 2020 23:53:30

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:33:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '17:35'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '12 Aug 2020 17:35'	System	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered empty.	System	12 Aug 2020 23:54:01

US3432120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:54:06

US3432120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	12 Aug 2020 23:54:06

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:49:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4952200c-ef8e-4ad7-9ff4-622118691270' User entered 'Yes (Y)'	System	12 Aug 2020 22:49:47
	System	12 Aug 2020 22:49:47

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:49:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4952200c-ef8e-4ad7-9ff4-622118691270' User entered '98.2'	System	12 Aug 2020 22:49:47
	System	12 Aug 2020 22:49:47

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:49:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4952200c-ef8e-4ad7-9ff4-622118691270' User entered 'No (N)'	System	12 Aug 2020 22:49:47
	System	12 Aug 2020 22:49:47

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:49:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4952200c-ef8e-4ad7-9ff4-622118691270' User entered '12 Aug 2020 18:49'	System	12 Aug 2020 22:49:47
	System	12 Aug 2020 22:49:47

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 21:09'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:50:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9a2809e6-e825-44d3-bf1e-006a726db39f' User entered 'Yes (Y)'	System	13 Aug 2020 02:50:53
	System	13 Aug 2020 02:50:53

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:50:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9a2809e6-e825-44d3-bf1e-006a726db39f' User entered '98.9'	System	13 Aug 2020 02:50:53
	System	13 Aug 2020 02:50:53

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:50:41', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9a2809e6-e825-44d3-bf1e-006a726db39f' User entered 'No (N)'	System	13 Aug 2020 02:50:53
	System	13 Aug 2020 02:50:53

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:50:48', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9a2809e6-e825-44d3-bf1e-006a726db39f' User entered '12 Aug 2020 22:50'	System	13 Aug 2020 02:50:53
	System	13 Aug 2020 02:50:53

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 22:04'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 2'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd38e66a4-5863-4c2e-b73c-cb48428cc1d1'	System	13 Aug 2020 17:50:45
User entered 'Yes (Y)'	System	13 Aug 2020 17:50:45

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd38e66a4-5863-4c2e-b73c-cb48428cc1d1' User entered '98.8'	System	13 Aug 2020 17:50:45
	System	13 Aug 2020 17:50:45

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd38e66a4-5863-4c2e-b73c-cb48428cc1d1'	System	13 Aug 2020 17:50:45
User entered 'No (N)'	System	13 Aug 2020 17:50:45

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:43', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd38e66a4-5863-4c2e-b73c-cb48428cc1d1'	System	13 Aug 2020 17:50:45
User entered '13 Aug 2020 13:50'	System	13 Aug 2020 17:50:45

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 3'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0038e714-ceda-453a-9650-810eb9efd67f' User entered 'Yes (Y)'	System	14 Aug 2020 16:31:26
	System	14 Aug 2020 16:31:26

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:17', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0038e714-ceda-453a-9650-810eb9efd67f' User entered '99.5'	System	14 Aug 2020 16:31:26
	System	14 Aug 2020 16:31:26

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0038e714-ceda-453a-9650-810eb9efd67f' User entered 'No (N)'	System	14 Aug 2020 16:31:26
	System	14 Aug 2020 16:31:26

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0038e714-ceda-453a-9650-810eb9efd67f' User entered '14 Aug 2020 12:31'	System	14 Aug 2020 16:31:26
	System	14 Aug 2020 16:31:26

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 4'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'cc7f132c-f05e-47c8-9d60-20188619b27d' User entered 'Yes (Y)'	System	15 Aug 2020 21:08:22
	System	15 Aug 2020 21:08:22

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'cc7f132c-f05e-47c8-9d60-20188619b27d' User entered '99.4'	System	15 Aug 2020 21:08:22
	System	15 Aug 2020 21:08:22

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:15', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'cc7f132c-f05e-47c8-9d60-20188619b27d' User entered 'No (N)'	System	15 Aug 2020 21:08:22
	System	15 Aug 2020 21:08:22

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'cc7f132c-f05e-47c8-9d60-20188619b27d' User entered '15 Aug 2020 17:08'	System	15 Aug 2020 21:08:22
	System	15 Aug 2020 21:08:22

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 5'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:43:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '05c9e801-5d6c-4f36-a63e-2e72df437e3c'	System	17 Aug 2020 02:43:57
User entered 'Yes (Y)'	System	17 Aug 2020 02:43:57

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:43:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '05c9e801-5d6c-4f36-a63e-2e72df437e3c' User entered '98.8'	System	17 Aug 2020 02:43:57
	System	17 Aug 2020 02:43:57

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:43:51', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '05c9e801-5d6c-4f36-a63e-2e72df437e3c'	System	17 Aug 2020 02:43:57
User entered 'No (N)'	System	17 Aug 2020 02:43:57

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:43:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '05c9e801-5d6c-4f36-a63e-2e72df437e3c' User entered '16 Aug 2020 22:43'	System	17 Aug 2020 02:43:57
	System	17 Aug 2020 02:43:57

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 6'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a70fcca5-497e-431b-878b-df2ead116302'	System	18 Aug 2020 03:59:27
User entered 'Yes (Y)'	System	18 Aug 2020 03:59:27

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:17', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a70fcca5-497e-431b-878b-df2ead116302'	System	18 Aug 2020 03:59:27
User entered '98.8'	System	18 Aug 2020 03:59:27

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:21', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a70fcca5-497e-431b-878b-df2ead116302'	System	18 Aug 2020 03:59:27
User entered 'No (N)'	System	18 Aug 2020 03:59:27

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:23', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a70fcca5-497e-431b-878b-df2ead116302'	System	18 Aug 2020 03:59:27
User entered '17 Aug 2020 23:59'	System	18 Aug 2020 03:59:27

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 7'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:16', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a15c80a7-43e5-4bce-98d0-63c7be3add1b' User entered 'Yes (Y)'	System	19 Aug 2020 03:59:30
	System	19 Aug 2020 03:59:30

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a15c80a7-43e5-4bce-98d0-63c7be3add1b' User entered '98.6'	System	19 Aug 2020 03:59:30
	System	19 Aug 2020 03:59:30

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a15c80a7-43e5-4bce-98d0-63c7be3add1b' User entered 'No (N)'	System	19 Aug 2020 03:59:30
	System	19 Aug 2020 03:59:30

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a15c80a7-43e5-4bce-98d0-63c7be3add1b' User entered '18 Aug 2020 23:59'	System	19 Aug 2020 03:59:30
	System	19 Aug 2020 03:59:30

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:49:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b53a7351-5e09-4406-af06-526ab4e9bc53'	System	12 Aug 2020 22:50:36
User entered 'None (1)'	System	12 Aug 2020 22:50:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b53a7351-5e09-4406-af06-526ab4e9bc53'	System	12 Aug 2020 22:50:36
User entered 'No (N)'	System	12 Aug 2020 22:50:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:21', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b53a7351-5e09-4406-af06-526ab4e9bc53'	System	12 Aug 2020 22:50:36
User entered 'No (N)'	System	12 Aug 2020 22:50:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b53a7351-5e09-4406-af06-526ab4e9bc53'	System	12 Aug 2020 22:50:36
User entered 'None (1)'	System	12 Aug 2020 22:50:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:35', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b53a7351-5e09-4406-af06-526ab4e9bc53'	System	12 Aug 2020 22:50:36
User entered '12 Aug 2020 18:50'	System	12 Aug 2020 22:50:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 21:09'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'dc36390f-e56a-4a38-bf25-e163b58f19ec'	System	13 Aug 2020 02:51:36
User entered 'None (1)'	System	13 Aug 2020 02:51:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'dc36390f-e56a-4a38-bf25-e163b58f19ec'	System	13 Aug 2020 02:51:36
User entered 'No (N)'	System	13 Aug 2020 02:51:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'dc36390f-e56a-4a38-bf25-e163b58f19ec'	System	13 Aug 2020 02:51:36
User entered 'No (N)'	System	13 Aug 2020 02:51:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'dc36390f-e56a-4a38-bf25-e163b58f19ec'	System	13 Aug 2020 02:51:36
User entered 'None (1)'	System	13 Aug 2020 02:51:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'dc36390f-e56a-4a38-bf25-e163b58f19ec'	System	13 Aug 2020 02:51:36
User entered '12 Aug 2020 22:51'	System	13 Aug 2020 02:51:36

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 22:04'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 2'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:50', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'fa1ec669-da57-4c88-aebc-8120635bbd48' User entered 'None (1)'	System	13 Aug 2020 17:51:03
	System	13 Aug 2020 17:51:03

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'fa1ec669-da57-4c88-aebc-8120635bbd48'	System	13 Aug 2020 17:51:03
User entered 'No (N)'	System	13 Aug 2020 17:51:03

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'fa1ec669-da57-4c88-aebc-8120635bbd48'	System	13 Aug 2020 17:51:03
User entered 'No (N)'	System	13 Aug 2020 17:51:03

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:50:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'fa1ec669-da57-4c88-aebc-8120635bbd48' User entered 'None (1)'	System	13 Aug 2020 17:51:03
	System	13 Aug 2020 17:51:03

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'fa1ec669-da57-4c88-aebc-8120635bbd48' User entered '13 Aug 2020 13:51'	System	13 Aug 2020 17:51:03
	System	13 Aug 2020 17:51:03

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 3'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8dd215cc-9c04-40ef-9b85-ab592187ee30' User entered 'None (1)'	System	14 Aug 2020 16:31:47
	System	14 Aug 2020 16:31:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8dd215cc-9c04-40ef-9b85-ab592187ee30'	System	14 Aug 2020 16:31:47
User entered 'No (N)'	System	14 Aug 2020 16:31:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8dd215cc-9c04-40ef-9b85-ab592187ee30'	System	14 Aug 2020 16:31:47
User entered 'No (N)'	System	14 Aug 2020 16:31:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8dd215cc-9c04-40ef-9b85-ab592187ee30' User entered 'None (1)'	System	14 Aug 2020 16:31:47
	System	14 Aug 2020 16:31:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8dd215cc-9c04-40ef-9b85-ab592187ee30' User entered '14 Aug 2020 12:31'	System	14 Aug 2020 16:31:47
	System	14 Aug 2020 16:31:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 4'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:23', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c3a0f6d6-120f-479b-8489-b298fec91c54' User entered 'None (1)'	System	15 Aug 2020 21:08:34
	System	15 Aug 2020 21:08:34

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c3a0f6d6-120f-479b-8489-b298fec91c54'	System	15 Aug 2020 21:08:34
User entered 'No (N)'	System	15 Aug 2020 21:08:34

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c3a0f6d6-120f-479b-8489-b298fec91c54'	System	15 Aug 2020 21:08:34
User entered 'No (N)'	System	15 Aug 2020 21:08:34

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c3a0f6d6-120f-479b-8489-b298fec91c54'	System	15 Aug 2020 21:08:34
User entered 'None (1)'	System	15 Aug 2020 21:08:34

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c3a0f6d6-120f-479b-8489-b298fec91c54'	System	15 Aug 2020 21:08:34
User entered '15 Aug 2020 17:08'	System	15 Aug 2020 21:08:34

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 5'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:43:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1ceab940-ad76-4d34-95ef-a65a02356741' User entered 'None (1)'	System	17 Aug 2020 02:44:11
	System	17 Aug 2020 02:44:11

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1ceab940-ad76-4d34-95ef-a65a02356741' User entered 'No (N)'	System	17 Aug 2020 02:44:11
	System	17 Aug 2020 02:44:11

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:02', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1ceab940-ad76-4d34-95ef-a65a02356741' User entered 'No (N)'	System	17 Aug 2020 02:44:11
	System	17 Aug 2020 02:44:11

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:04', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1ceab940-ad76-4d34-95ef-a65a02356741' User entered 'None (1)'	System	17 Aug 2020 02:44:11
	System	17 Aug 2020 02:44:11

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1ceab940-ad76-4d34-95ef-a65a02356741' User entered '16 Aug 2020 22:44'	System	17 Aug 2020 02:44:11
	System	17 Aug 2020 02:44:11

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 6'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7ae959e-a5f1-40a9-bbb1-3ea6489d367b' User entered 'None (1)'	System	18 Aug 2020 03:59:40
	System	18 Aug 2020 03:59:40

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7ae959e-a5f1-40a9-bbb1-3ea6489d367b' User entered 'No (N)'	System	18 Aug 2020 03:59:40
	System	18 Aug 2020 03:59:40

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7ae959e-a5f1-40a9-bbb1-3ea6489d367b' User entered 'No (N)'	System	18 Aug 2020 03:59:40
	System	18 Aug 2020 03:59:40

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7ae959e-a5f1-40a9-bbb1-3ea6489d367b' User entered 'None (1)'	System	18 Aug 2020 03:59:40
	System	18 Aug 2020 03:59:40

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7ae959e-a5f1-40a9-bbb1-3ea6489d367b' User entered '17 Aug 2020 23:59'	System	18 Aug 2020 03:59:40
	System	18 Aug 2020 03:59:40

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 7'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '482c325c-4392-4124-b5f1-61d159ab4411'	System	19 Aug 2020 03:59:47
User entered 'None (1)'	System	19 Aug 2020 03:59:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '482c325c-4392-4124-b5f1-61d159ab4411'	System	19 Aug 2020 03:59:47
User entered 'No (N)'	System	19 Aug 2020 03:59:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '482c325c-4392-4124-b5f1-61d159ab4411' User entered 'No (N)'	System	19 Aug 2020 03:59:47
	System	19 Aug 2020 03:59:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:41', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '482c325c-4392-4124-b5f1-61d159ab4411' User entered 'None (1)'	System	19 Aug 2020 03:59:47
	System	19 Aug 2020 03:59:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '482c325c-4392-4124-b5f1-61d159ab4411' User entered '18 Aug 2020 23:59'	System	19 Aug 2020 03:59:47
	System	19 Aug 2020 03:59:47

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:48', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:53', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:50:57', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:51:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:51:04', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:51:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'None (0)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:51:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered 'No (N)'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T18:51:17', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f6cbcd32-781e-4d0a-9b4d-ce6cf64323c1' User entered '12 Aug 2020 18:51'	System	12 Aug 2020 22:51:19
	System	12 Aug 2020 22:51:19

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 21:09'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:48', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a'	System	13 Aug 2020 02:52:17
User entered 'No interference with activity (1)'	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:53', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'None (0)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'None (0)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:51:59', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'None (0)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:52:02', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'None (0)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:52:04', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'None (0)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:52:08', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered 'No (N)'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-12T22:52:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '19433dcf-65d7-41eb-bcf6-7486ce01913a' User entered '12 Aug 2020 22:52'	System	13 Aug 2020 02:52:17
	System	13 Aug 2020 02:52:17

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Aug 2020 22:04'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 2'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:16', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207'	System	13 Aug 2020 17:52:29
User entered 'No interference with activity (1)'	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered 'None (0)'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered 'None (0)'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered 'None (0)'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:44', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207'	System	13 Aug 2020 17:52:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:46', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered 'None (0)'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:51:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered 'No (N)'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-13T13:52:26', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '423085f1-056f-4249-b585-80cc8ccb8207' User entered '13 Aug 2020 13:52'	System	13 Aug 2020 17:52:29
	System	13 Aug 2020 17:52:29

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 3'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:31:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5'	System	14 Aug 2020 16:33:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5'	System	14 Aug 2020 16:33:04
User entered 'Some interference with activity (2)'	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:08', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5' User entered 'None (0)'	System	14 Aug 2020 16:33:04
	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5' User entered 'None (0)'	System	14 Aug 2020 16:33:04
	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5'	System	14 Aug 2020 16:33:04
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5'	System	14 Aug 2020 16:33:04
User entered 'Some interference with activity not requiring medical attention (2)'	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:32:48', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5' User entered 'No (N)'	System	14 Aug 2020 16:33:04
	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-14T12:33:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c4f92e63-85bb-49f2-ac40-d2cc4a2acac5' User entered '14 Aug 2020 12:33'	System	14 Aug 2020 16:33:04
	System	14 Aug 2020 16:33:04

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 4'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:40', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:41', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:43', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:44', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'None (0)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:47', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46' User entered 'No (N)'	System	15 Aug 2020 21:08:54
	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-15T17:08:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f27888bd-9e0a-4180-8531-64b41c5eea46'	System	15 Aug 2020 21:08:54
User entered '15 Aug 2020 17:08'	System	15 Aug 2020 21:08:54

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 5'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'None (0)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:19', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'None (0)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'None (0)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'None (0)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd'	System	17 Aug 2020 02:44:42
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'None (0)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered 'No (N)'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-16T22:44:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '266234bb-a8c3-4c8a-add0-7629dfd30ddd' User entered '16 Aug 2020 22:44'	System	17 Aug 2020 02:44:42
	System	17 Aug 2020 02:44:42

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 6'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:47', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:50', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:53', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-17T23:59:57', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'None (0)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T00:00:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered 'No (N)'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T00:00:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0fe2e97e-9778-4df9-a620-9423b8db712d' User entered '18 Aug 2020 00:00'	System	18 Aug 2020 04:00:07
	System	18 Aug 2020 04:00:07

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 7'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:51', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-18T23:59:57', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-19T00:00:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-19T00:00:02', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-19T00:00:04', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'None (0)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-19T00:00:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b' User entered 'No (N)'	System	19 Aug 2020 04:00:13
	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-08-19T00:00:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd374a800-7fa7-41b9-a4ef-f2a5b84be83b'	System	19 Aug 2020 04:00:13
User entered '19 Aug 2020 00:00'	System	19 Aug 2020 04:00:13

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:46:16

US3432120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:02:23

US3432120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:02:23

US3432120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:02:23

US3432120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 13:02:23

US3432120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:02:28

US3432120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	19 Aug 2020 13:02:28

US3432120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:48:56

US3432120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:48:56

US3432120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:48:56

US3432120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 20:48:56

US3432120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:49:00

US3432120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	26 Aug 2020 20:49:00

US3432120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	03 Sep 2020 12:40:06

US3432120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '2 Sep 2020'	Phoebe Cunningham (b) (4)	03 Sep 2020 12:40:06

US3432120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	03 Sep 2020 12:40:06

US3432120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	03 Sep 2020 12:40:06

US3432120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	08 Sep 2020 15:56:09

US3432120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	08 Sep 2020 15:56:09

US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:09:31

US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 08:25:42
User closed query 'Per CDM: Please update the date to the correct format (DD MMM YYYY).' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:25:38
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		16 Sep 2020 23:54:27
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Per protocol, visit window can be -3/+7 from D29.' (Site from System).	Jun Bai Park Chang (b) (4)	15 Sep 2020 16:01:16
Query 'Per CDM: Please update the date to the correct format (DD MMM YYYY).' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	15 Sep 2020 15:55:27
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Sep 2020 15:52:02
User entered '08 Sep 2020' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	15 Sep 2020 15:52:02
User opened query 'Per CDM: Please update the date to the correct format (DD MMM YYYY).' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:38:08
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 10:37:34
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Protocol allows a 3 day window, please update query to read as follows: "Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates"' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 23:12:02
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Sep 2020 23:09:31

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EAB) (1725)

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US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:09:31

US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 23:09:31

US3432120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'VISIT2'	System	08 Sep 2020 23:09:31

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '10:56'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '8 Sep 2020 10:56'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '36.4' C	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '61'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'bpm'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '12'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'breaths/min'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '122'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '84'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:16:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 23:16:37
User entered '12:30' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:16:37
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:16:28
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '8 Sep 2020 12:30'	System	08 Sep 2020 23:16:37
User entered empty.	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:17:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 23:17:08
User entered '36.4' C reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:17:08
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 23:16:28
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:17:08
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '88'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'bpm'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'breaths/min'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '132'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '70'	(b) (4), (b) (6)	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	08 Sep 2020 23:16:28

US3432120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:17:17

US3432120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:17:17

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Urine (URINE)'	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered empty.	System	08 Sep 2020 23:17:36

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

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)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '8 Sep 2020'	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '11:50'	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '8 Sep 2020 11:50'	System	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Left Arm (LEFT ARM)'	Jessica Cauley (b) (4)	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'ONCE'	System	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:56:43

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:18:24

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per GCL Lab Recon: Re-query: Immunogenicity: Response noted, however please confirm if this sample collected for UNSCHEDULED visit on 08SEP2020. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:25:21
Query 'Per GCL Lab Recon: Re-query: Immunogenicity: Response noted, however please confirm if this sample collected for UNSCHEDULED visit on 08SEP2020. Else clarify, thank you.' answered with 'This sample was collected for Visit 2 Day 29 and was corrected on PPD to reflect this.' (Site from DM).	Jun Bai Park Chang (b) (4)	12 Nov 2020 14:06:36
User opened query 'Per GCL Lab Recon: Re-query: Immunogenicity: Response noted, however please confirm if this sample collected for UNSCHEDULED visit on 08SEP2020. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:22:33
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:22:33
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate. ' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 15:05:13

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate. ' (Site from DM). User entered '8 Sep 2020'	(b) (4), (b) (6)	24 Oct 2020 16:20:09
	(b) (4), (b) (6)	08 Sep 2020 23:18:24

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '11:22'	(b) (4), (b) (6)	08 Sep 2020 23:18:24

US3432120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '8 Sep 2020 11:22'	System	08 Sep 2020 23:18:24

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:03:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 15:05:01
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:58:46
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '11:26'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 09:48:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:59:14
User entered '8 Sep 2020 11:26'	System	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered empty.	System	08 Sep 2020 23:18:51

US3432120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:17:40

US3432120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '1'	System	08 Sep 2020 23:17:40

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:32:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5e091ee9-79ea-4aae-a4f5-0824cb0ec4e6' User entered 'Yes (Y)'	System	08 Sep 2020 16:33:12
	System	08 Sep 2020 16:33:12

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5e091ee9-79ea-4aae-a4f5-0824cb0ec4e6' User entered '97.6'	System	08 Sep 2020 16:33:12
	System	08 Sep 2020 16:33:12

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5e091ee9-79ea-4aae-a4f5-0824cb0ec4e6'	System	08 Sep 2020 16:33:12
User entered 'No (N)'	System	08 Sep 2020 16:33:12

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:10', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5e091ee9-79ea-4aae-a4f5-0824cb0ec4e6' User entered '08 Sep 2020 12:33'	System	08 Sep 2020 16:33:12
	System	08 Sep 2020 16:33:12

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 12:10'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 14:40'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:05', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '99c4466a-f558-46b5-919d-af544a736567' User entered 'Yes (Y)'	System	09 Sep 2020 02:38:20
	System	09 Sep 2020 02:38:20

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:10', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '99c4466a-f558-46b5-919d-af544a736567' User entered '98.5'	System	09 Sep 2020 02:38:20
	System	09 Sep 2020 02:38:20

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:12', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '99c4466a-f558-46b5-919d-af544a736567'	System	09 Sep 2020 02:38:20
User entered 'No (N)'	System	09 Sep 2020 02:38:20

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:16', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '99c4466a-f558-46b5-919d-af544a736567' User entered '08 Sep 2020 22:38'	System	09 Sep 2020 02:38:20
	System	09 Sep 2020 02:38:20

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 2'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:52:46', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a0ea0698-877e-47ff-93dc-a93043a1a4f5' User entered 'No (N)'	System	10 Sep 2020 01:53:10
	System	10 Sep 2020 01:53:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:52:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a0ea0698-877e-47ff-93dc-a93043a1a4f5'	System	10 Sep 2020 01:53:10
User entered 'Yes (Y)'	System	10 Sep 2020 01:53:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt contacted and tylenol added to conmeds' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 08:44:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a0ea0698-877e-47ff-93dc-a93043a1a4f5' User entered '1'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:32:41
	System	10 Sep 2020 01:53:10
	System	10 Sep 2020 01:53:10
	System	10 Sep 2020 01:53:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a0ea0698-877e-47ff-93dc-a93043a1a4f5' User entered '0'	System	10 Sep 2020 01:53:10
	System	10 Sep 2020 01:53:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a0ea0698-877e-47ff-93dc-a93043a1a4f5' User entered '09 Sep 2020 21:53'	System	10 Sep 2020 01:53:10
	System	10 Sep 2020 01:53:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 3'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:05', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5f55c4ff-f02a-48dc-891a-3750f0f54349'	System	11 Sep 2020 03:49:18
User entered 'Yes (Y)'	System	11 Sep 2020 03:49:18

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5f55c4ff-f02a-48dc-891a-3750f0f54349' User entered '97.3'	System	11 Sep 2020 03:49:18
	System	11 Sep 2020 03:49:18

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5f55c4ff-f02a-48dc-891a-3750f0f54349'	System	11 Sep 2020 03:49:18
User entered 'No (N)'	System	11 Sep 2020 03:49:18

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:16', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5f55c4ff-f02a-48dc-891a-3750f0f54349'	System	11 Sep 2020 03:49:18
User entered '10 Sep 2020 23:49'	System	11 Sep 2020 03:49:18

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 4'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:41:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd44de2c0-3939-4695-8154-53598418e9dc' User entered 'Yes (Y)'	System	11 Sep 2020 19:42:10
	System	11 Sep 2020 19:42:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:41:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd44de2c0-3939-4695-8154-53598418e9dc' User entered '98.5'	System	11 Sep 2020 19:42:10
	System	11 Sep 2020 19:42:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd44de2c0-3939-4695-8154-53598418e9dc'	System	11 Sep 2020 19:42:10
User entered 'No (N)'	System	11 Sep 2020 19:42:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd44de2c0-3939-4695-8154-53598418e9dc'	System	11 Sep 2020 19:42:10
User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 5'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4b4ae84b-ec18-498f-b2a1-ee1f0244b07a' User entered 'Yes (Y)'	System	13 Sep 2020 03:22:25
	System	13 Sep 2020 03:22:25

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4b4ae84b-ec18-498f-b2a1-ee1f0244b07a' User entered '98.4'	System	13 Sep 2020 03:22:25
	System	13 Sep 2020 03:22:25

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:17', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4b4ae84b-ec18-498f-b2a1-ee1f0244b07a'	System	13 Sep 2020 03:22:25
User entered 'No (N)'	System	13 Sep 2020 03:22:25

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4b4ae84b-ec18-498f-b2a1-ee1f0244b07a' User entered '12 Sep 2020 23:22'	System	13 Sep 2020 03:22:25
	System	13 Sep 2020 03:22:25

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 6'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:10', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '43efea4a-4d13-44ca-82cd-779a0667429f' User entered 'Yes (Y)'	System	14 Sep 2020 10:16:23
	System	14 Sep 2020 10:16:23

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:15', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '43efea4a-4d13-44ca-82cd-779a0667429f' User entered '98.3'	System	14 Sep 2020 10:16:23
	System	14 Sep 2020 10:16:23

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '43efea4a-4d13-44ca-82cd-779a0667429f' User entered 'No (N)'	System	14 Sep 2020 10:16:23
	System	14 Sep 2020 10:16:23

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:21', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '43efea4a-4d13-44ca-82cd-779a0667429f' User entered '14 Sep 2020 06:16'	System	14 Sep 2020 10:16:23
	System	14 Sep 2020 10:16:23

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 7'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T06:54:23', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7602d957-1dc3-4d29-824e-48767e79ce91'	System	15 Sep 2020 11:03:10
User entered 'Yes (Y)'	System	15 Sep 2020 11:03:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T06:54:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7602d957-1dc3-4d29-824e-48767e79ce91' User entered '98.3'	System	15 Sep 2020 11:03:10
	System	15 Sep 2020 11:03:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:04', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7602d957-1dc3-4d29-824e-48767e79ce91'	System	15 Sep 2020 11:03:10
User entered 'No (N)'	System	15 Sep 2020 11:03:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7602d957-1dc3-4d29-824e-48767e79ce91' User entered '15 Sep 2020 07:03'	System	15 Sep 2020 11:03:10
	System	15 Sep 2020 11:03:10

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f01ceee-1125-47df-a934-c6be18ba178d' User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 16:33:54
	System	08 Sep 2020 16:33:54

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f01ceee-1125-47df-a934-c6be18ba178d' User entered 'No (N)'	System	08 Sep 2020 16:33:54
	System	08 Sep 2020 16:33:54

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:37', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f01ceee-1125-47df-a934-c6be18ba178d' User entered 'No (N)'	System	08 Sep 2020 16:33:54
	System	08 Sep 2020 16:33:54

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f01ceee-1125-47df-a934-c6be18ba178d' User entered 'None (1)'	System	08 Sep 2020 16:33:54
	System	08 Sep 2020 16:33:54

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:33:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f01ceee-1125-47df-a934-c6be18ba178d' User entered '08 Sep 2020 12:33'	System	08 Sep 2020 16:33:54
	System	08 Sep 2020 16:33:54

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 12:10'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 14:40'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '6f367892-1014-4cb0-8916-a4004ad179ee'	System	09 Sep 2020 02:38:38
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 02:38:38

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '6f367892-1014-4cb0-8916-a4004ad179ee' User entered 'No (N)'	System	09 Sep 2020 02:38:38
	System	09 Sep 2020 02:38:38

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '6f367892-1014-4cb0-8916-a4004ad179ee' User entered 'No (N)'	System	09 Sep 2020 02:38:38
	System	09 Sep 2020 02:38:38

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '6f367892-1014-4cb0-8916-a4004ad179ee' User entered 'None (1)'	System	09 Sep 2020 02:38:38
	System	09 Sep 2020 02:38:38

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '6f367892-1014-4cb0-8916-a4004ad179ee' User entered '08 Sep 2020 22:38'	System	09 Sep 2020 02:38:38
	System	09 Sep 2020 02:38:38

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 2'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:10', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7705300-ab70-4334-ba03-de79d53271ef' User entered 'None (1)'	System	10 Sep 2020 01:53:31
	System	10 Sep 2020 01:53:31

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7705300-ab70-4334-ba03-de79d53271ef' User entered 'No (N)'	System	10 Sep 2020 01:53:31
	System	10 Sep 2020 01:53:31

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7705300-ab70-4334-ba03-de79d53271ef' User entered 'No (N)'	System	10 Sep 2020 01:53:31
	System	10 Sep 2020 01:53:31

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7705300-ab70-4334-ba03-de79d53271ef' User entered 'None (1)'	System	10 Sep 2020 01:53:31
	System	10 Sep 2020 01:53:31

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'a7705300-ab70-4334-ba03-de79d53271ef' User entered '09 Sep 2020 21:53'	System	10 Sep 2020 01:53:31
	System	10 Sep 2020 01:53:31

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 3'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:19', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4c16cca0-4e7c-4f99-93c3-bbed3d22da91'	System	11 Sep 2020 03:49:36
User entered 'None (1)'	System	11 Sep 2020 03:49:36

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4c16cca0-4e7c-4f99-93c3-bbed3d22da91' User entered 'No (N)'	System	11 Sep 2020 03:49:36
	System	11 Sep 2020 03:49:36

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4c16cca0-4e7c-4f99-93c3-bbed3d22da91' User entered 'No (N)'	System	11 Sep 2020 03:49:36
	System	11 Sep 2020 03:49:36

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:27', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4c16cca0-4e7c-4f99-93c3-bbed3d22da91' User entered 'None (1)'	System	11 Sep 2020 03:49:36
	System	11 Sep 2020 03:49:36

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '4c16cca0-4e7c-4f99-93c3-bbed3d22da91' User entered '10 Sep 2020 23:49'	System	11 Sep 2020 03:49:36
	System	11 Sep 2020 03:49:36

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 4'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1b9b5a1b-ed02-4e93-ae67-7e0f99f36ba1'	System	11 Sep 2020 19:42:16
User entered 'None (1)'	System	11 Sep 2020 19:42:16

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1b9b5a1b-ed02-4e93-ae67-7e0f99f36ba1' User entered 'No (N)'	System	11 Sep 2020 19:42:16
	System	11 Sep 2020 19:42:16

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1b9b5a1b-ed02-4e93-ae67-7e0f99f36ba1' User entered 'No (N)'	System	11 Sep 2020 19:42:16
	System	11 Sep 2020 19:42:16

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1b9b5a1b-ed02-4e93-ae67-7e0f99f36ba1'	System	11 Sep 2020 19:42:16
User entered 'None (1)'	System	11 Sep 2020 19:42:16

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:15', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1b9b5a1b-ed02-4e93-ae67-7e0f99f36ba1'	System	11 Sep 2020 19:42:16
User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:16

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 5'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:24', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2b53c3eb-bf3c-400e-8883-9c8f75a156b1' User entered 'None (1)'	System	13 Sep 2020 03:22:41
	System	13 Sep 2020 03:22:41

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2b53c3eb-bf3c-400e-8883-9c8f75a156b1' User entered 'No (N)'	System	13 Sep 2020 03:22:41
	System	13 Sep 2020 03:22:41

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2b53c3eb-bf3c-400e-8883-9c8f75a156b1' User entered 'No (N)'	System	13 Sep 2020 03:22:41
	System	13 Sep 2020 03:22:41

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2b53c3eb-bf3c-400e-8883-9c8f75a156b1' User entered 'None (1)'	System	13 Sep 2020 03:22:41
	System	13 Sep 2020 03:22:41

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2b53c3eb-bf3c-400e-8883-9c8f75a156b1' User entered '12 Sep 2020 23:22'	System	13 Sep 2020 03:22:41
	System	13 Sep 2020 03:22:41

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 6'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '85a593ed-0f7c-4b86-b6e9-414b49b34c24' User entered 'None (1)'	System	14 Sep 2020 10:16:45
	System	14 Sep 2020 10:16:45

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '85a593ed-0f7c-4b86-b6e9-414b49b34c24' User entered 'No (N)'	System	14 Sep 2020 10:16:45
	System	14 Sep 2020 10:16:45

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '85a593ed-0f7c-4b86-b6e9-414b49b34c24' User entered 'No (N)'	System	14 Sep 2020 10:16:45
	System	14 Sep 2020 10:16:45

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '85a593ed-0f7c-4b86-b6e9-414b49b34c24' User entered 'None (1)'	System	14 Sep 2020 10:16:45
	System	14 Sep 2020 10:16:45

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '85a593ed-0f7c-4b86-b6e9-414b49b34c24' User entered '14 Sep 2020 06:16'	System	14 Sep 2020 10:16:45
	System	14 Sep 2020 10:16:45

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 7'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '35ddabe0-f219-4e06-b19f-9849bb807410' User entered 'None (1)'	System	15 Sep 2020 11:03:28
	System	15 Sep 2020 11:03:28

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:15', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '35ddabe0-f219-4e06-b19f-9849bb807410' User entered 'No (N)'	System	15 Sep 2020 11:03:28
	System	15 Sep 2020 11:03:28

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '35ddabe0-f219-4e06-b19f-9849bb807410' User entered 'No (N)'	System	15 Sep 2020 11:03:28
	System	15 Sep 2020 11:03:28

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '35ddabe0-f219-4e06-b19f-9849bb807410' User entered 'None (1)'	System	15 Sep 2020 11:03:28
	System	15 Sep 2020 11:03:28

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:26', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '35ddabe0-f219-4e06-b19f-9849bb807410' User entered '15 Sep 2020 07:03'	System	15 Sep 2020 11:03:28
	System	15 Sep 2020 11:03:28

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:21', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:23', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'None (0)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:44', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered 'No (N)'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T12:34:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e18e8c01-28bf-4f80-806d-938ebaa4c6a1' User entered '08 Sep 2020 12:34'	System	08 Sep 2020 16:34:51
	System	08 Sep 2020 16:34:51

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 12:10'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 14:40'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:40', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29'	System	09 Sep 2020 02:39:03
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29'	System	09 Sep 2020 02:39:03
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:44', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29' User entered 'None (0)'	System	09 Sep 2020 02:39:03
	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:46', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29' User entered 'None (0)'	System	09 Sep 2020 02:39:03
	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:50', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29'	System	09 Sep 2020 02:39:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29' User entered 'None (0)'	System	09 Sep 2020 02:39:03
	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:57', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29' User entered 'No (N)'	System	09 Sep 2020 02:39:03
	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-08T22:38:59', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9f42a8f5-7544-4d22-b092-79ca070fef29' User entered '08 Sep 2020 22:38'	System	09 Sep 2020 02:39:03
	System	09 Sep 2020 02:39:03

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 2'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c'	System	10 Sep 2020 01:54:13
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c'	System	10 Sep 2020 01:54:13
User entered 'No interference with activity (1)'	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c' User entered 'None (0)'	System	10 Sep 2020 01:54:13
	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:43', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c' User entered 'None (0)'	System	10 Sep 2020 01:54:13
	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:46', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c'	System	10 Sep 2020 01:54:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c' User entered 'None (0)'	System	10 Sep 2020 01:54:13
	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:53:57', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c' User entered 'No (N)'	System	10 Sep 2020 01:54:13
	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-09T21:54:08', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '5da863a3-04b7-414a-909b-c3c5d443f51c' User entered '09 Sep 2020 21:54'	System	10 Sep 2020 01:54:13
	System	10 Sep 2020 01:54:13

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 3'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad'	System	11 Sep 2020 03:49:56
User entered 'No interference with activity (1)'	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:40', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad'	System	11 Sep 2020 03:49:56
User entered 'No interference with activity (1)'	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered 'None (0)'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:44', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered 'None (0)'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:47', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered 'None (0)'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered 'None (0)'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered 'No (N)'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-10T23:49:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8869e159-7a3c-4d72-998d-8278930ce2ad' User entered '10 Sep 2020 23:49'	System	11 Sep 2020 03:49:56
	System	11 Sep 2020 03:49:56

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 4'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:26', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:28', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'None (0)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'None (0)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'None (0)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'None (0)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:35', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered 'No (N)'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-11T15:42:37', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '412beae9-44e8-42ee-9bf9-bb66c6a6cf4f' User entered '11 Sep 2020 15:42'	System	11 Sep 2020 19:42:45
	System	11 Sep 2020 19:42:45

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 5'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:43', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:51', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:53', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:22:56', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'None (0)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:23:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered 'No (N)'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-12T23:23:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'c6732d81-5a86-46a9-9fc4-d375e012ecdc' User entered '12 Sep 2020 23:23'	System	13 Sep 2020 03:23:04
	System	13 Sep 2020 03:23:04

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 6'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:46', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:48', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:50', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:51', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:53', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:16:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'None (0)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:17:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered 'No (N)'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-14T06:17:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '82d79097-193a-45a1-b101-72fcc130b911' User entered '14 Sep 2020 06:17'	System	14 Sep 2020 10:17:09
	System	14 Sep 2020 10:17:09

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	08 Sep 2020 15:56:43
User entered 'Day 7'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:34', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:35', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'None (0)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

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)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered 'No (N)'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-09-15T07:03:41', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '2be0e7c9-5c14-4ad5-9586-da361d0bb47a' User entered '15 Sep 2020 07:03'	System	15 Sep 2020 11:03:44
	System	15 Sep 2020 11:03:44

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:56:43

US3432120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:56:43

US3432120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 12:38:52

US3432120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 12:38:52

US3432120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 12:38:52

US3432120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 12:38:52

US3432120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:06:09

US3432120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	22 Sep 2020 13:06:09

US3432120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:07:40

US3432120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 13:07:40

US3432120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 13:07:40

US3432120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:07:40

US3432120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:13:10

US3432120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	22 Sep 2020 13:13:10

US3432120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 12:36:48

US3432120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 12:36:48

US3432120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 12:36:48

US3432120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 12:36:48

US3432120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 12:41:17

US3432120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	05 Oct 2020 12:41:17

US3432120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:53:43

US3432120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '09 Oct 2020'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:53:43

US3432120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:53:43

US3432120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'VISIT3'	System	09 Oct 2020 20:53:43

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '09 Oct 2020'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '15:51'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '09 Oct 2020 15:51'	System	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '97.8' F	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'Oral (Oral)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered empty.	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '78'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'bpm'	System	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '15'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'breaths/min'	System	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '113'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '073'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'mmHg'	System	09 Oct 2020 20:54:50

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37

US3432120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37

US3432120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'No (N)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:55

US3432120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered empty.	Natalie Izaguirre (b) (4)	09 Oct 2020 20:54:55

US3432120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:55:09

US3432120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '09 Oct 2020'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:55:09

US3432120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:30:23
User entered '15:57'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:55:09

US3432120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered '09 Oct 2020 15:57'	System	09 Oct 2020 20:55:09

US3432120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	09 Oct 2020 20:55:13

US3432120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	09 Oct 2020 20:55:13

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 64'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-12T11:25:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8610605c-a322-4354-80a0-c1520d413994'	System	12 Oct 2020 15:25:32
User entered 'No (N)'	System	12 Oct 2020 15:25:32

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-12T11:25:26', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8610605c-a322-4354-80a0-c1520d413994'	System	12 Oct 2020 15:25:32
User entered 'No (N)'	System	12 Oct 2020 15:25:32

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-12T11:25:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8610605c-a322-4354-80a0-c1520d413994'	System	12 Oct 2020 15:25:32
User entered '12 Oct 2020 11:25:29'	System	12 Oct 2020 15:25:32

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 71'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-19T21:15:55', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f789e0a9-c450-4e70-837f-bbee311cb5fd' User entered 'No (N)'	System	20 Oct 2020 01:16:06
	System	20 Oct 2020 01:16:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-19T21:15:58', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f789e0a9-c450-4e70-837f-bbee311cb5fd' User entered 'No (N)'	System	20 Oct 2020 01:16:06
	System	20 Oct 2020 01:16:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-19T21:16:01', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'f789e0a9-c450-4e70-837f-bbee311cb5fd' User entered '19 Oct 2020 21:16:01'	System	20 Oct 2020 01:16:06
	System	20 Oct 2020 01:16:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 78'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-26T15:49:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd4b28235-ae7e-42e2-aa69-87647442dbbe' User entered 'No (N)'	System	26 Oct 2020 19:49:17
	System	26 Oct 2020 19:49:17

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-26T15:49:13', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd4b28235-ae7e-42e2-aa69-87647442dbbe' User entered 'No (N)'	System	26 Oct 2020 19:49:17
	System	26 Oct 2020 19:49:17

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-10-26T15:49:15', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd4b28235-ae7e-42e2-aa69-87647442dbbe' User entered '26 Oct 2020 15:49:15'	System	26 Oct 2020 19:49:17
	System	26 Oct 2020 19:49:17

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 92'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-12T11:02:39', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad061af4-91af-4c48-886c-a3f7fd50fe11' User entered 'No (N)'	System	12 Nov 2020 16:02:47
	System	12 Nov 2020 16:02:47

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-12T11:02:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad061af4-91af-4c48-886c-a3f7fd50fe11'	System	12 Nov 2020 16:02:47
User entered 'No (N)'	System	12 Nov 2020 16:02:47

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-12T11:02:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad061af4-91af-4c48-886c-a3f7fd50fe11' User entered '12 Nov 2020 11:02:45'	System	12 Nov 2020 16:02:47
	System	12 Nov 2020 16:02:47

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:35:22
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06
Data entry locked.	System	12 Aug 2020 22:46:16
User entered 'Day 99'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 22:46:16

US3432120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:32:06
Data entry locked.	System	12 Aug 2020 22:46:16
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 22:46:16

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-20T18:20:36', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '93b51c2e-59cb-4a79-9ee8-89db702ebf98'	System	20 Nov 2020 23:20:45
User entered 'No (N)'	System	20 Nov 2020 23:20:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-20T18:20:38', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '93b51c2e-59cb-4a79-9ee8-89db702ebf98' User entered 'No (N)'	System	20 Nov 2020 23:20:45
	System	20 Nov 2020 23:20:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-20T18:20:40', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '93b51c2e-59cb-4a79-9ee8-89db702ebf98' User entered '20 Nov 2020 18:20:40'	System	20 Nov 2020 23:20:45
	System	20 Nov 2020 23:20:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-30T17:30:35', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7c18bc08-09b8-4081-839e-d330a526be67'	System	30 Nov 2020 22:30:47
User entered 'No (N)'	System	30 Nov 2020 22:30:47

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-30T17:30:42', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7c18bc08-09b8-4081-839e-d330a526be67'	System	30 Nov 2020 22:30:47
User entered 'No (N)'	System	30 Nov 2020 22:30:47

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-11-30T17:30:45', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7c18bc08-09b8-4081-839e-d330a526be67' User entered '30 Nov 2020 17:30:45'	System	30 Nov 2020 22:30:47

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-04T00:11:16', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '67924e16-fb66-4acb-b2cc-5d1931a0bd6f' User entered 'No (N)'	System	04 Dec 2020 05:11:26
	System	04 Dec 2020 05:11:26

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-04T00:11:19', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '67924e16-fb66-4acb-b2cc-5d1931a0bd6f' User entered 'No (N)'	System	04 Dec 2020 05:11:26
	System	04 Dec 2020 05:11:26

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-04T00:11:23', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '67924e16-fb66-4acb-b2cc-5d1931a0bd6f' User entered '04 Dec 2020 00:11:23'	System	04 Dec 2020 05:11:26
	System	04 Dec 2020 05:11:26

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-13T17:13:19', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '27556e7b-c2f8-49a5-a01a-35c5964a19fb' User entered 'No (N)'	System	13 Dec 2020 22:13:31

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-13T17:13:26', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '27556e7b-c2f8-49a5-a01a-35c5964a19fb' User entered 'No (N)'	System	13 Dec 2020 22:13:31
	System	13 Dec 2020 22:13:31

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-13T17:13:30', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '27556e7b-c2f8-49a5-a01a-35c5964a19fb' User entered '13 Dec 2020 17:13:30'	System	13 Dec 2020 22:13:31
	System	13 Dec 2020 22:13:31

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-20T12:01:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'bbe9067e-4921-4ccb-87e7-10f64a3926c9' User entered 'No (N)'	System	20 Dec 2020 17:01:57
	System	20 Dec 2020 17:01:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-20T12:01:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'bbe9067e-4921-4ccb-87e7-10f64a3926c9' User entered 'No (N)'	System	20 Dec 2020 17:01:57
	System	20 Dec 2020 17:01:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-20T12:01:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'bbe9067e-4921-4ccb-87e7-10f64a3926c9' User entered '20 Dec 2020 12:01:54'	System	20 Dec 2020 17:01:57
	System	20 Dec 2020 17:01:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:35', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500'	System	28 Dec 2020 20:47:50
User entered 'Yes (Y)'	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500' User entered 'No (N)'	System	28 Dec 2020 20:47:50
	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:32', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500' User entered 'No (N)'	System	28 Dec 2020 20:47:50
	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500'	System	28 Dec 2020 20:47:50
User entered 'Yes (Y)'	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:31', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500'	System	28 Dec 2020 20:47:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2020-12-28T15:47:40', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '0e2245be-9c71-4228-84ce-12baee8ee500' User entered '28 Dec 2020 15:47:40'	System	28 Dec 2020 20:47:50
	System	28 Dec 2020 20:47:50

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b' User entered 'Yes (Y)'	System	01 Jan 2021 13:51:43
	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b' User entered 'No (N)'	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b' User entered 'No (N)'	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b' User entered 'Yes (Y)'	System	01 Jan 2021 13:51:43
	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:29', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b'	System	01 Jan 2021 13:51:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-01T08:51:33', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7af3cfe0-8ccf-4681-bd65-eb730b0c308b' User entered '01 Jan 2021 08:51:33'	System	01 Jan 2021 13:51:43
	System	01 Jan 2021 13:51:43

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-10T12:00:09', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'df4f3261-73c5-4407-ac74-0524d73e4ee5'	System	10 Jan 2021 17:00:17
User entered 'No (N)'	System	10 Jan 2021 17:00:17

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-10T12:00:11', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'df4f3261-73c5-4407-ac74-0524d73e4ee5'	System	10 Jan 2021 17:00:17
User entered 'No (N)'	System	10 Jan 2021 17:00:17

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-10T12:00:14', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'df4f3261-73c5-4407-ac74-0524d73e4ee5' User entered '10 Jan 2021 12:00:14'	System	10 Jan 2021 17:00:17
	System	10 Jan 2021 17:00:17

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-18T16:12:02', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '84d755e4-0b2b-4461-9d95-0d4f19a27bfd' User entered 'No (N)'	System	18 Jan 2021 21:12:08
	System	18 Jan 2021 21:12:08

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-18T16:12:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '84d755e4-0b2b-4461-9d95-0d4f19a27bfd' User entered 'No (N)'	System	18 Jan 2021 21:12:08
	System	18 Jan 2021 21:12:08

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-18T16:12:06', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '84d755e4-0b2b-4461-9d95-0d4f19a27bfd' User entered '18 Jan 2021 16:12:06'	System	18 Jan 2021 21:12:08
	System	18 Jan 2021 21:12:08

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-25T17:25:20', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '3d0add7c-6c19-4eae-aed1-8c64ca30857a' User entered 'No (N)'	System	26 Jan 2021 21:36:28
	System	26 Jan 2021 21:36:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-25T17:25:22', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '3d0add7c-6c19-4eae-aed1-8c64ca30857a' User entered 'No (N)'	System	26 Jan 2021 21:36:28
	System	26 Jan 2021 21:36:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-25T17:25:24', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '3d0add7c-6c19-4eae-aed1-8c64ca30857a' User entered '25 Jan 2021 17:25:24'	System	26 Jan 2021 21:36:28
	System	26 Jan 2021 21:36:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-29T05:28:18', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b8fcf6ea-a36f-4b27-b01d-d09f7fe56d93'	System	29 Jan 2021 10:28:28
User entered 'No (N)'	System	29 Jan 2021 10:28:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-29T05:28:21', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b8fcf6ea-a36f-4b27-b01d-d09f7fe56d93'	System	29 Jan 2021 10:28:28
User entered 'No (N)'	System	29 Jan 2021 10:28:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-01-29T05:28:25', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'b8fcf6ea-a36f-4b27-b01d-d09f7fe56d93' User entered '29 Jan 2021 05:28:25'	System	29 Jan 2021 10:28:28
	System	29 Jan 2021 10:28:28

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-05T00:03:05', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd7a6cc3d-676a-41f8-b1ab-ba01cbcb48e' User entered 'No (N)'	System	05 Feb 2021 05:03:21
	System	05 Feb 2021 05:03:21

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-05T00:03:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd7a6cc3d-676a-41f8-b1ab-ba01cbcbe48e' User entered 'No (N)'	System	05 Feb 2021 05:03:21
	System	05 Feb 2021 05:03:21

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-05T00:03:10', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd7a6cc3d-676a-41f8-b1ab-ba01cbcb48e' User entered '05 Feb 2021 00:03:10'	System	05 Feb 2021 05:03:21
	System	05 Feb 2021 05:03:21

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-15T16:08:03', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e74a0020-805a-4aaa-9acb-b615cfead778'	System	15 Feb 2021 21:08:09
User entered 'No (N)'	System	15 Feb 2021 21:08:09

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-15T16:08:05', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e74a0020-805a-4aaa-9acb-b615cfead778'	System	15 Feb 2021 21:08:09
User entered 'No (N)'	System	15 Feb 2021 21:08:09

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-15T16:08:07', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e74a0020-805a-4aaa-9acb-b615cfead778' User entered '15 Feb 2021 16:08:07'	System	15 Feb 2021 21:08:09
	System	15 Feb 2021 21:08:09

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-19T06:49:49', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '29a567e4-436c-4fde-9d5d-34fa535189e1' User entered 'No (N)'	System	22 Feb 2021 18:20:14
	System	22 Feb 2021 18:20:14

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-19T06:49:52', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '29a567e4-436c-4fde-9d5d-34fa535189e1' User entered 'No (N)'	System	22 Feb 2021 18:20:14
	System	22 Feb 2021 18:20:14

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-02-19T06:49:54', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '29a567e4-436c-4fde-9d5d-34fa535189e1' User entered '19 Feb 2021 06:49:54'	System	22 Feb 2021 18:20:14
	System	22 Feb 2021 18:20:14

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-02T12:01:02-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad672b33-826f-42ed-8767-b67dc589f7c2'	System	02 Mar 2021 17:03:45
User entered 'No (N)'	System	02 Mar 2021 17:03:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-02T12:01:05-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad672b33-826f-42ed-8767-b67dc589f7c2'	System	02 Mar 2021 17:03:45
User entered 'No (N)'	System	02 Mar 2021 17:03:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-02T12:01:08-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'ad672b33-826f-42ed-8767-b67dc589f7c2'	System	02 Mar 2021 17:03:45
User entered '02 Mar 2021 12:01:08'	System	02 Mar 2021 17:03:45

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-05T06:01:39-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8e788bbd-416b-4898-bdfd-476a1712e18c'	System	05 Mar 2021 11:01:54
User entered 'No (N)'	System	05 Mar 2021 11:01:54

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-05T06:01:44-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8e788bbd-416b-4898-bdfd-476a1712e18c'	System	05 Mar 2021 11:01:54
User entered 'No (N)'	System	05 Mar 2021 11:01:54

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-05T06:01:47-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '8e788bbd-416b-4898-bdfd-476a1712e18c' User entered '05 Mar 2021 06:01:47'	System	05 Mar 2021 11:01:54
	System	05 Mar 2021 11:01:54

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-13T10:36:54-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9d7d6409-a1dd-4a29-8d1a-29c4e98ce0e5'	System	13 Mar 2021 15:37:07
User entered 'No (N)'	System	13 Mar 2021 15:37:07

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-13T10:36:56-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9d7d6409-a1dd-4a29-8d1a-29c4e98ce0e5'	System	13 Mar 2021 15:37:07
User entered 'No (N)'	System	13 Mar 2021 15:37:07

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-13T10:37:04-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '9d7d6409-a1dd-4a29-8d1a-29c4e98ce0e5' User entered '13 Mar 2021 10:37:04'	System	13 Mar 2021 15:37:07
	System	13 Mar 2021 15:37:07

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-21T09:02:12-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '984320b8-8ff2-412f-8068-cbfdc8bcd524'	System	23 Mar 2021 16:16:57
User entered 'No (N)'	System	23 Mar 2021 16:16:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-21T09:02:15-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '984320b8-8ff2-412f-8068-cbfdc8bcd524'	System	23 Mar 2021 16:16:57
User entered 'No (N)'	System	23 Mar 2021 16:16:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-21T09:02:18-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '984320b8-8ff2-412f-8068-cbfcd8bcd524'	System	23 Mar 2021 16:16:57
User entered '21 Mar 2021 09:02:18'	System	23 Mar 2021 16:16:57

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-29T18:04:28-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd9052d8e-cff3-4085-b3c6-186e620f2888'	System	29 Mar 2021 22:10:49
User entered 'No (N)'	System	29 Mar 2021 22:10:49

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-29T18:04:30-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd9052d8e-cff3-4085-b3c6-186e620f2888'	System	29 Mar 2021 22:10:49
User entered 'No (N)'	System	29 Mar 2021 22:10:49

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-29T18:04:33-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'd9052d8e-cff3-4085-b3c6-186e620f2888'	System	29 Mar 2021 22:10:49
User entered '29 Mar 2021 18:04:33'	System	29 Mar 2021 22:10:49

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-02T05:46:43-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1f8d8b01-a413-4f3b-8db7-87c752547372'	System	02 Apr 2021 09:46:53
User entered 'No (N)'	System	02 Apr 2021 09:46:53

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-02T05:46:45-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1f8d8b01-a413-4f3b-8db7-87c752547372'	System	02 Apr 2021 09:46:53
User entered 'No (N)'	System	02 Apr 2021 09:46:53

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-02T05:46:50-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '1f8d8b01-a413-4f3b-8db7-87c752547372'	System	02 Apr 2021 09:46:53
User entered '02 Apr 2021 05:46:50'	System	02 Apr 2021 09:46:53

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-12T16:53:30-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e8ac6929-1242-4072-ad76-2643272223fc' User entered 'No (N)'	System	12 Apr 2021 20:53:42
	System	12 Apr 2021 20:53:42

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-12T16:53:31-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e8ac6929-1242-4072-ad76-2643272223fc' User entered 'No (N)'	System	12 Apr 2021 20:53:42
	System	12 Apr 2021 20:53:42

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-12T16:53:33-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'e8ac6929-1242-4072-ad76-2643272223fc' User entered '12 Apr 2021 16:53:33'	System	12 Apr 2021 20:53:42
	System	12 Apr 2021 20:53:42

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:16-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered 'Yes (Y)'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:04-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered 'No (N)'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:03-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered 'No (N)'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:02-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered 'Yes (Y)'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Please 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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:20-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-16T05:43:23-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '7cbe6696-5aae-4f87-91a0-a0ab6f3e9dc5'	System	16 Apr 2021 09:43:35
User entered '16 Apr 2021 05:43:23'	System	16 Apr 2021 09:43:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-23T07:31:25-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'eca7af27-c2ad-459a-9bd8-fc13bd8eaa93'	System	23 Apr 2021 11:31:35
User entered 'No (N)'	System	23 Apr 2021 11:31:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

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 (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-23T07:31:27-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'eca7af27-c2ad-459a-9bd8-fc13bd8eaa93'	System	23 Apr 2021 11:31:35
User entered 'No (N)'	System	23 Apr 2021 11:31:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-04-23T07:31:30-04:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: 'eca7af27-c2ad-459a-9bd8-fc13bd8eaa93'	System	23 Apr 2021 11:31:35
User entered '23 Apr 2021 07:31:30'	System	23 Apr 2021 11:31:35

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:32:06

US3432120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:32:06
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:32:06

US3432120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:33:05

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)	26 Apr 2021 09:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-02T12:00:54-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '91aad8b-cdc8-4de0-bcf7-7ba7f55f4f5c'	System	02 Mar 2021 17:03:41
User entered 'No (N)'	System	02 Mar 2021 17:03:41

US3432120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:33:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56ADB93B-7CE0-47DE-9062-F60C4C2D87B1)', Time: '2021-03-02T12:00:58-05:00', User OID: 'PatientReportedOutcome (US3432120)', ODM File OID: '91aad8b-cdc8-4de0-bcf7-7ba7f55f4f5c'	System	02 Mar 2021 17:03:41
User entered '02 Mar 2021 12:00:58'	System	02 Mar 2021 17:03:41

US3432120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 19:39:23

US3432120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 19:39:23

US3432120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 19:39:23

US3432120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 19:39:23

US3432120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 13:15:26

US3432120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:30:37
User entered 'I'	System	04 Dec 2020 13:15:26

US3432120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 13:18:18

US3432120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '4 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 13:18:18

US3432120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Dec 2020 13:18:18

US3432120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 13:18:18

US3432120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 13:18:41

US3432120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User entered 'I'	System	04 Dec 2020 13:18:41

US3432120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 13:28:22

US3432120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '4 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 13:28:22

US3432120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Jan 2021 13:28:22

US3432120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 13:28:22

US3432120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 13:28:27

US3432120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User entered 'I'	System	04 Jan 2021 13:28:27

US3432120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	03 Feb 2021 19:25:58

US3432120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '3 Feb 2021'	Tenaizus Woods (b) (4)	03 Feb 2021 19:25:58

US3432120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	03 Feb 2021 19:25:58

US3432120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Tenaizus Woods (b) (4)	03 Feb 2021 19:25:58

US3432120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	03 Feb 2021 19:26:01

US3432120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:02
User entered 'I'	System	03 Feb 2021 19:26:01

US3432120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:02:15

US3432120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:02:15

US3432120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Mar 2021 21:02:15

US3432120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'VISIT4'	System	12 Mar 2021 21:02:15

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12 Mar 2021'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '15:42'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered '12 Mar 2021 15:42'	System	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '36.8' C	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '72'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'bpm'	System	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'breaths/min'	System	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '111'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'mmHg'	System	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '74'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'mmHg'	System	31 Mar 2021 20:19:30

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40

US3432120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40

US3432120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:02:32

US3432120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:02:32

US3432120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:02:44

US3432120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:02:44

US3432120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '15:50'	(b) (4), (b) (6)	12 Mar 2021 21:02:44

US3432120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered '12 Mar 2021 15:50'	System	12 Mar 2021 21:02:44

US3432120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:02:50

US3432120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:26:40
User entered 'I'	System	12 Mar 2021 21:02:50

US3432120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:02:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:53:14

US3432120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:02:02
User entered '5 Apr 2021'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:53:14

US3432120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:02:02
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:53:14

US3432120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:02:02
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:53:14

US3432120

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:02:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) [REDACTED]	05 Apr 2021 17:53:18

US3432120

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:53:18

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 and 02OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 03:59:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 and 02OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	19 Feb 2021 21:21:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 and 02OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:13:36
User entered '29 Sep 2020'	Xhoi Mitre (b) (4)	29 Sep 2020 22:35:36

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12:25'	Xhoi Mitre (b) (4)	29 Sep 2020 22:35:36

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:28
User entered '29 Sep 2020 12:25'	System	29 Sep 2020 22:35:36

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:35:36

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:35:36

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Day 1 (Day 1)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '28 Sep 2020'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User entered '%'	System	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:33:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:03

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Day 2 (Day 2)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '29 Sep 2020'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User entered '%'	System	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '36.7' C	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:33:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	29 Sep 2020 22:36:43

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Day 3 (Day 3)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '30 Sep 2020'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'I'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User entered '%'	System	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:33:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:05

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Day 4 (Day 4)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '01 Oct 2020'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User entered '%'	System	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98.1' F	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:33:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	01 Oct 2020 21:27:40

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Day 5 (Day 5)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '02 Oct 2020'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '100'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User entered '%'	System	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98.2' F	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:33:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'None (None)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:55:07

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:32:30
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	19 Feb 2021 21:21:50
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:31:20
User entered '29 Sep 2020'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[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 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[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 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'No (N)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '29 Sep 2020'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[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 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'No (N)'	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Xhoi Mitre (b) (4)	05 Oct 2020 20:56:25

US3432120

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:33:05

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:35:19
User entered '0'	System	05 Oct 2020 20:56:25

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 3 (Day 3)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '01 Oct 2020'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 5 (Day 5)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '02 Oct 2020'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 7 (Day 7)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 9 (Day 9)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 14 (Day 14)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 21 (Day 21)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:33:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User accepted default value 'Day 28 (Day 28)'	Austin Kim (b) (4) (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:33:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:21:37

US3432120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '29 Sep 2020'	Austin Kim (b) (4)	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Clinic (Clinic)'	Austin Kim (b) (4)	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered 'SICKD1'	System	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Per CDM: Vital signs is performed on 29 Sep 2020 for Unscheduled_29 SEP 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 17:41:19
Query 'Per CDM: Vital signs is performed on 29 Sep 2020 for Unscheduled_29 SEP 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' answered with 'they are duplicates' (Site from DM).	Austin Kim (b) (4)	05 Mar 2021 16:14:05
User opened query 'Per CDM: Vital signs is performed on 29 Sep 2020 for Unscheduled_29 SEP 2020 as well as Illness Visit Day 1 , kindly review if they are duplicates else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:06:19
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '29 Sep 2020'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '12:27'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered '29 Sep 2020 12:27'	System	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 21:20:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Feb 2021 21:20:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Austin Kim (b) (4)	19 Feb 2021 21:20:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 21:20:23
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:20:23
DataPoint set to visible.	(b) (4) System	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 21:20:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Feb 2021 21:20:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Austin Kim (b) (4)	19 Feb 2021 21:20:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 21:20:23
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:20:23
DataPoint set to visible.	(b) (4) System	19 Feb 2021 21:20:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '36.7' C	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Oral (Oral)'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '75'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered 'bpm'	System	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '16'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered 'breaths/min'	System	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '105'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered 'mmHg'	System	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '74'	Austin Kim (b) (4)	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User entered 'mmHg'	System	19 Feb 2021 21:20:23

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01

US3432120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:20:39

US3432120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '29 Sep 2020'	Austin Kim (b) (4)	19 Feb 2021 21:20:39

US3432120

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:33:05

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Austin Kim (b) (4)	19 Feb 2021 21:20:45

US3432120

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:33:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:01
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '29 Sep 2020'	Austin Kim (b) (4)	19 Feb 2021 21:20:45

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 21:58:18

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 21:58:18

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

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 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 21:58:18

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:58:18

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:58:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:58:36
User entered '19 Jan 2021' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	19 Jan 2021 21:58:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:20:55
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[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 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	07 Apr 2021 20:50:59
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:46:16

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:58:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:58:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	19 Jan 2021 21:58:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:20:55
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	Monica Feeley (b) (4)	07 Apr 2021 20:50:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:46:16

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021' reason for change: Data Entry Error	Jun Bai Park Chang	19 Jan 2021 21:58:36
User entered empty.	(b) (4)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Placebo (Placebo)' reason for change:	Jun Bai Park Chang	19 Jan 2021 21:58:36
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:55:36
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Jun Bai Park Chang	19 Jan 2021 21:58:36
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:55:36
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Jun Bai Park Chang	19 Jan 2021 21:58:36
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang	19 Jan 2021 21:58:36
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '1'	System	19 Jan 2021 21:58:36
User entered empty.	System	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:33:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'I'	System	19 Jan 2021 21:58:36
User entered empty.	System	19 Jan 2021 21:20:55

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	19 Jan 2021 22:01:10
DataPoint set to visible.	System	19 Jan 2021 21:58:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	19 Jan 2021 22:01:10
DataPoint set to visible.	System	19 Jan 2021 21:58:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User accepted default value 'Pre-Dose (PREDOSE)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '14:28'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '19 Jan 2021 14:28'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98.1' F	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '78'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'bpm'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '14'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'breaths/min'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '141'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '68'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	19 Jan 2021 22:01:10
DataPoint set to visible.	System	19 Jan 2021 21:58:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User accepted default value 'Post-Dose (POSTDOSE)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '16:10'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '19 Jan 2021 16:10'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '98.1' F	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '74'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'bpm'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '14'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'breaths/min'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '116'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '73'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mmHg'	System	19 Jan 2021 22:01:10

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:17

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:17

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Urine (URINE)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Negative (NEGATIVE)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered empty.	System	19 Jan 2021 22:01:25

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

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)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'mRNA-1273'	System	19 Jan 2021 22:01:39
DataPoint set to visible.	System	19 Jan 2021 21:58:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '15:40'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '19 Jan 2021 15:40'	System	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Left Arm (LEFT ARM)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'ONCE'	System	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 22:01:39

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:27

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:27

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '14:32'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:27

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '19 Jan 2021 14:32'	System	19 Jan 2021 22:09:27

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:05

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '19 Jan 2021'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '14:38'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:09:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '19 Jan 2021 14:38'	System	19 Jan 2021 22:09:36

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	19 Jan 2021 22:01:43

US3432120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:44:46
User entered '1'	System	19 Jan 2021 22:01:43

US3432120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	26 Jan 2021 21:08:16

US3432120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '26 Jan 2021'	Kathleen Garvey (b) (4)	26 Jan 2021 21:08:16

US3432120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	26 Jan 2021 21:08:16

US3432120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Kathleen Garvey (b) (4)	26 Jan 2021 21:08:16

US3432120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	26 Jan 2021 21:09:15

US3432120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User entered 'I'	System	26 Jan 2021 21:09:15

US3432120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:03
User entered '1'	System	26 Jan 2021 21:09:15
DataPoint set to visible.	System	26 Jan 2021 21:09:15

US3432120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:07:09

US3432120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Feb 2021'	Bruce Bausk (b) (4)	02 Mar 2021 15:07:09

US3432120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	02 Mar 2021 15:07:09

US3432120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'OLD29'	System	02 Mar 2021 15:07:09

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Feb 2021'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '15:43'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered '26 Feb 2021 15:43'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '97.1' F	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Other (Other)'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'IR'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '74'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'bpm'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '14'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'breaths/min'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '105'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'mmHg'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '69'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'mmHg'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Feb 2021'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '16:52'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered '26 Feb 2021 16:52'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '97.1' F	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Other (Other)'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'IR'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '72'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'bpm'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '14'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'breaths/min'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '128'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'mmHg'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '64'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'mmHg'	System	02 Mar 2021 15:08:23

US3432120

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:29

US3432120

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:36
User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:36
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:36
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:36
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:36
User entered '26 Feb 2021' reason for change: Data Entry Error	Bruce Bausk (b) (4)	02 Mar 2021 15:08:36
User opened query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	02 Mar 2021 15:08:29
User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:29
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:29
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	02 Mar 2021 15:08:29
User entered '26 Feb 2020'	Bruce Bausk (b) (4)	02 Mar 2021 15:08:29

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Feb 2021'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Urine (URINE)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Negative (NEGATIVE)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'No (N)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Bruce Bausk (b) (4)	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered empty.	System	02 Mar 2021 15:09:07

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

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)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'mRNA-1273'	System	02 Mar 2021 15:09:24
DataPoint set to visible.	System	26 Jan 2021 21:09:15

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Feb 2021'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '16:22'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered '26 Feb 2021 16:22'	System	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'ONCE'	System	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 15:09:24

US3432120

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	02 Mar 2021 15:09:27

US3432120

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:59:23
User entered 'I'	System	02 Mar 2021 15:09:27

US3432120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 19:13:01

US3432120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '05 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 19:13:01

US3432120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Mar 2021 19:13:01

US3432120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:13:01

US3432120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 19:13:06

US3432120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:06:16
User entered 'I'	System	05 Mar 2021 19:13:06

US3432120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Monica Feeley (b) (4)	29 Mar 2021 12:33:38

US3432120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Mar 2021'	Monica Feeley (b) (4)	29 Mar 2021 12:33:38

US3432120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4)	29 Mar 2021 12:33:38

US3432120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered 'OLD57'	System	29 Mar 2021 12:33:38

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Mar 2021'	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '15:40' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered '26 Mar 2021 15:40'	System	29 Mar 2021 12:34:11
User entered empty.	System	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '36.3' C reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '087' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered 'bpm'	System	29 Mar 2021 12:34:11
User entered empty.	System	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '014' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered 'breaths/min'	System	29 Mar 2021 12:34:11
User entered empty.	System	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '116' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered 'mmHg'	System	29 Mar 2021 12:34:11
User entered empty.	System	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 12:34:11
User entered '068' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 12:33:47
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered 'mmHg'	System	29 Mar 2021 12:34:11
User entered empty.	System	29 Mar 2021 12:33:47

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43

US3432120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43

US3432120

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'No (N)'	Monica Feeley (b) (4)	29 Mar 2021 12:34:15

US3432120

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered empty.	Monica Feeley (b) (4)	29 Mar 2021 12:34:15

US3432120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered 'Yes (Y)'	Monica Feeley (b) (4)	29 Mar 2021 12:34:40

US3432120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '26 Mar 2021'	Monica Feeley (b) (4)	29 Mar 2021 12:34:40

US3432120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '15:45'	Monica Feeley (b) (4)	29 Mar 2021 12:34:40

US3432120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:42:43
User entered '26 Mar 2021 15:45'	System	29 Mar 2021 12:34:40

US3432120

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:33:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:28:30

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Mental impairment (excl dementia and memory loss), PT: Disturbance in attention, LLT: Poor concentration - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:14:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:14:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Coordination and balance disturbances, PT: Coordination abnormal, LLT: Lack of coordination - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:13:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:13:50
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Mental impairment (excl dementia and memory loss), PT: Disturbance in attention, LLT: Concentration loss - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:09:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:09:21
Data point term sent to Coder System	System	19 Aug 2020 21:29:42
User entered 'lack of concentration'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:31:26
Query 'Per CDM: Response is required. Please provide.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Oct 2020 23:03:59
User entered 'No (N)'	Monica Feeley (b) (4)	21 Oct 2020 23:03:48
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:56:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:17:11
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 15:56:43
User entered '13 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:14:55
Query 'Data is required. Please provide.' answered with '24 hours after dosing' (Site from System).	Xhoi Mitre (b) (4)	19 Aug 2020 21:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:29:35
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User entered empty.	System	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '14 Aug 2020'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:14:57
Query 'Data is required. Please provide.' answered with '24 hours after dosing ' (Site from System).	Xhoi Mitre (b) (4)	19 Aug 2020 21:32:48
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:29:35
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User entered empty.	System	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Related (RELATED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'I'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:29:35

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
Amendment Manager: User entered '0'	System	21 Aug 2020 04:02:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
Amendment Manager: User entered '0'	System	21 Aug 2020 04:02:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:04:37
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:31:35
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'unknown etiology' (Site from DM).	Monica Feeley (b) (4)	21 Oct 2020 23:04:17
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:16:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Dysphonia, LLT: Hoarse voice - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:33:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:33:12
Data point term sent to Coder	System	19 Aug 2020 21:32:47
User entered 'Hoarse Voice'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:31:38
Query 'Per CDM: Response is required. Please provide.' answered with 'updated ' (Site from DM).	Monica Feeley (b) (4)	21 Oct 2020 23:05:03
User entered 'No (N)'	Monica Feeley (b) (4)	21 Oct 2020 23:04:56
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:56:57
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:17:18
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 15:56:43
User entered '15 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User entered empty.	System	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '16 Aug 2020'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User entered empty.	System	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'I'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Xhoi Mitre (b) (4)	19 Aug 2020 21:31:57

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
Amendment Manager: User entered '0'	System	21 Aug 2020 04:02:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
Amendment Manager: User entered '0'	System	21 Aug 2020 04:02:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:34
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 04:02:07

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Mental impairment (excl dementia and memory loss), PT: Disturbance in attention, LLT: Poor concentration - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:29:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:29:52
Data point term sent to Coder	System	08 Sep 2020 23:29:17
User entered 'Lack of Concentration'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '12:05'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User entered '8 Sep 2020 12:05'	System	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)' reason for change: New Information	Phoebe Cunningham (b) (4)	15 Sep 2020 21:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '9 Sep 2020' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	15 Sep 2020 21:02:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 10:35:33
Query 'Data is required. Please provide.' answered with 'MORE THAN 24 HRS FROM VACCINATION' (Site from System).	Phoebe Cunningham (b) (4)	15 Sep 2020 21:02:19
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 21:02:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User entered empty.	System	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:30:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:30:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:30:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:28:46
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:30:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:30:11
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:30:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:28:46
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:30:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:30:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:30:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:28:46
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:30:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:30:11
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:30:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:28:46
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	15 Sep 2020 21:02:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Similar to prior episode'	(b) (4), (b) (6)	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User entered '0'	System	08 Sep 2020 23:30:11

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11
User entered '0'	System	08 Sep 2020 23:28:46

US3432120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:11

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:45:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:45:35
Data point term sent to Coder	System	21 Oct 2020 23:45:19
User entered 'Upper respiratory infection'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Yes (Y)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '28 Sep 2020'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User entered empty.	System	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:45:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:45:22
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Oct 2020 23:45:22
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:45:14
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '30 Sep 2020'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User entered empty.	System	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'I'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Monica Feeley (b) (4)	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User entered '0'	System	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16
User entered 'I'	System	21 Oct 2020 23:45:14

US3432120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:16

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Radius fracture, LLT: Radius fracture - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 10:22:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 10:22:25
Data point term sent to Coder	System	28 Dec 2020 23:03:58
User entered 'Fractured left distal radius'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Yes (Y)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '25 Dec 2020'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User entered empty.	System	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:22:22
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'UPDATED' (Site from DM).	Monica Feeley (b) (4)	29 Mar 2021 12:36:48
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:36:43
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:10:12
User entered 'Yes (Y)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '16 Mar 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:36:43
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User entered empty.	System	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Not Related (NOT RELATED)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'None (NONE)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'I'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:50:19
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	05 Mar 2021 16:12:31
User entered '1' reason for change: Data Entry Error	(b) (4)	05 Mar 2021 16:12:26
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:59:09
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Monica Feeley (b) (4)	29 Mar 2021 12:36:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User entered '0'	System	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23
User entered 'I'	System	28 Dec 2020 23:03:48

US3432120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:15:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:22:02
User entered	System	04 Feb 2021 12:21:10
'USA-US078-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 12:21:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:38:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:38:51
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 23:50:08
User entered 'SBO (small bowel obstruction)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'No (N)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'No (N)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	28 Mar 2021 20:26:49
User closed query 'per source AE, symptoms started from 30Jan, please check if start date will change to 30Jan21.' (Site from CRA).	(b) (4), (b) (6)	28 Mar 2021 20:26:47
Query 'per source AE, symptoms started from 30Jan, please check if start date will change to 30Jan21.' answered with 'updated to 30Jan2021' (Site from CRA).	Monica Feeley (b) (4)	24 Mar 2021 16:53:32
DataPoint Un-verified.	(b) (4)	
	Monica Feeley (b) (4)	24 Mar 2021 16:53:12
User entered '30 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'per source AE, symptoms started from 30Jan, please check if start date will change to 30Jan21.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:40:59
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '31 Jan 2021'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:21:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:33:19
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:33:06
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:21:12
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:34:58
User entered empty.	System	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'I'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '31 Jan 2021'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '02 Feb 2021'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'No (N)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 15:44:06
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' answered with 'updated to none' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:59:53
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 18:59:35
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 14 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:36:14
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	17 Mar 2021 05:05:37
User closed query 'Per CDM re-query: Thank you for the response. Please add the con med once data is available. Please ensure the con med indication term to match AE term to reconcile data. Please leave the query open till an update made else respond to clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
Query 'Per CDM re-query: Thank you for the response. Please add the con med once data is available. Please ensure the con med indication term to match AE term to reconcile data. Please leave the query open till an update made else respond to clarify. ' answered with 'we have added the con med that the participant remembers' (Site from DM).	Monica Feeley (b) (4)	16 Mar 2021 13:18:26
User opened query 'Per CDM re-query: Thank you for the response. Please add the con med once data is available. Please ensure the con med indication term to match AE term to reconcile data. Please leave the query open till an update made else respond to clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:35:05
Query 'Per CDM re-query: Thank you for the response. Please add the con med once data is available. Please ensure the con med indication term to match AE term to reconcile data. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:33:00
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:32:54
User opened query 'Per CDM re-query: Thank you for the response. Please add the con med once data is available. Please ensure the con med indication term to match AE term to reconcile data. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:32:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'pain medication and anti nausea medication. obtaining details from participant. will update when information obtained' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Mar 2021 19:51:07
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Feb 2021 16:15:24
User entered 'I'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:14:41
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	Monica Feeley (b) (4)	24 Mar 2021 16:50:54
answered with 'please see con procedures, they are entered' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:10:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Mar 2021 19:52:47
User entered '0'	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	09 Apr 2021 14:49:17
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'not really sure what we are supposed to do because we are being told we need all queries resolved. This will not be resolved until sometime in the summer because that is when the participant will have surgery for it. until then it is ongoing. We have a lot of queries open for ongoing SAEs that are not going to end anytime soon, so getting conflicting information about what to do..' (Site from Safety).	Monica Feeley (b) (4)	07 Apr 2021 20:53:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:49:15
Query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:49:04
User opened query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:03:46
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:03:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'As of SC239, Condition is still ongoing.' (Site from Safety).	Tenaizus Woods (b) (4)	05 Apr 2021 17:57:39
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:35:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 23:50:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 23:50:05
	(b) (4)	

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:44:33
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	29 Mar 2021 12:37:35
	(b) (4)	
User entered 'PARTICIPANT REPORTS A SMALL BOWEL OBSTRUCTION THAT LEAD TO A HOSPITAL STAY FROM 1/31/2021 TO 2/2/2021.	Monica Feeley (b) (4)	29 Mar 2021 12:37:35
	(b) (4)	
SMALL BOWEL XRAY: SHOWS SMALL BOWEL OBSTRUCTION CT ABDOMEN AND PELVIS: SHOWS SMALL BOWEL OBSTRUCTION WITH TRANSITION POINT IN THE RIGHT LOWER QUADRANT		
Reports NP covid test done 31JAN2021- negative' reason for change: Data Entry Error		
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:18:57
	(b) (4)	
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'participant does not recall if COVID-19 testing was performed. confirmed' (Site from Safety).	Monica Feeley (b) (4)	24 Mar 2021 16:51:20
	(b) (4)	
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 13:35:56
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:36:04
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'we have updated the con med logs' (Site from Safety).	Monica Feeley (b) (4)	16 Mar 2021 13:18:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4)	
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:34:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:51:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:51:01
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:50:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'these have been sent to this email' (Site from Safety).	Monica Feeley (b) (4)	10 Mar 2021 20:13:00
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pain medication and anti nausea medication. obtaining details from participant' (Site from Safety).	Monica Feeley (b) (4)	10 Mar 2021 19:50:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'small bowel xray: shows small bowel obstruction CT abdomen and pelvis: shows small bowel obstruction with transition point in the right lower quadrant' (Site from Safety).	Monica Feeley (b) (4)	10 Mar 2021 19:49:49
User entered 'PARTICIPANT REPORTS A SMALL BOWEL OBSTRUCTION THAT LEAD TO A HOSPITAL STAY FROM 1/31/2021 TO 2/2/2021.	Monica Feeley (b) (4)	10 Mar 2021 19:49:44

small bowel xray: shows small bowel obstruction
CT abdomen and pelvis: shows small bowel
obstruction with transition point in the right lower
quadrant' reason for change: Data Entry Error

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:37:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:36:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:35:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:34:19
User entered 'Participant reports a small bowel obstruction that lead to a hospital stay from 1/31/2021 to 2/2/2021.'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 23:50:05

US3432120

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:33:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 23:50:05

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:33:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:45:28

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
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)	12 Aug 2020 23:47:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 23:47:18
Data point term sent to Coder	System	12 Aug 2020 23:46:21
User entered 'Multivitamin'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 12:59:02
Query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:34:36
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 15:30:04
User opened query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:23:20
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'General Health'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'capsule (CAPSULE)'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'once daily (QD)'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
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 00:54:40
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.' answered with 'per protocol' (Site from System).	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:56
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	12 Aug 2020 23:46:03
User entered 'un UNK 2010'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham	12 Aug 2020 23:46:03
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 23:46:03

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 23:48:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 23:48:19
Data point term sent to Coder	System	12 Aug 2020 23:47:24
User entered 'Calcium'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:00:14
Query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:35:06
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 15:35:02
User opened query 'Per DM CLR: Indication = GENERAL HEALTH. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:23:36
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'General Health'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '500'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'mg (mg)'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'once daily (QD)'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
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 00:54:45
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.'	Phoebe Cunningham	12 Aug 2020 23:46:48
answered with 'per protocol' (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	12 Aug 2020 23:46:42
User entered 'un UNK 2010'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham	12 Aug 2020 23:46:42
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 23:46:42

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:36:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:36:49
Data point term sent to Coder Coding entries removed.	System Natalie Izaguirre (b) (4)	18 Nov 2020 22:36:03 18 Nov 2020 22:35:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 13:04:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 13:04:20
Data point term sent to Coder User entered 'Tylenol'	System Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:57 19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	01 Dec 2020 19:19:29
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	Natalie Izaguirre (b) (4)	18 Nov 2020 22:36:04
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'headache (reactogenicity)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	18 Nov 2020 22:35:48
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	01 Oct 2020 06:46:21
' (Site from DM).		
User entered 'Head foginess'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1000'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'as needed (PRN)' reason for change:	Natalie Izaguirre (b) (4)	18 Nov 2020 22:35:48
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Phoebe Cunningham	19 Aug 2020 13:03:44
	(b) (4)	

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '13 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '13 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User entered empty.	System	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User entered empty.	System	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:05
User entered empty.	System	19 Aug 2020 13:03:44

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:35:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:35:44
Data point term sent to Coder User entered 'tylenol'	System Phoebe Cunningham (b) (4)	15 Sep 2020 13:34:44 15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:23:21
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'No AE needed. Headaches reported for this date in Ediary 2. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:36:00

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:48:23
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:25:45
User entered '650' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Dec 2020 13:25:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:38:58
Data hard unlocked.	(b) (4), (b) (6)	03 Oct 2020 05:38:55
Data hard locked.	(b) (4), (b) (6)	03 Oct 2020 05:38:52
User entered '2'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Dec 2020 13:25:36
User entered 'tablet (TABLET)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'once (ONCE)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '9 Sep 2020'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '9 Sep 2020'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User entered empty.	System	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User entered empty.	System	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:09
User entered empty.	System	15 Sep 2020 13:33:49

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 23:06:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 23:06:24
Data point term sent to Coder	System	28 Dec 2020 23:05:59
User entered 'Tylenol'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Fractured arm'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '500'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'mg (mg)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'as needed (PRN)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '25 Dec 2020'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6) Tenaizus Woods (b) (4)	19 Apr 2021 14:52:39 05 Apr 2021 17:57:00
Signature has been broken.	Tenaizus Woods (b) (4)	05 Apr 2021 17:56:54
User entered 'No (N)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	05 Apr 2021 17:56:54
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 14:11:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
Signature has been broken.	Tenaizus Woods (b) (4)	05 Apr 2021 17:56:54
User entered '20 Feb 2021' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	05 Apr 2021 17:56:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User entered empty.	System	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User entered empty.	System	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:15
User entered empty.	System	28 Dec 2020 23:05:04

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 13:11:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 13:11:16
Data point term sent to Coder	System	28 Dec 2020 23:08:00
User entered 'Ibuprofen'	Bethany Evans (b) (4) (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Fractured arm'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '600'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'mg (mg)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'as needed (PRN)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Oral (ORAL)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '25 Dec 2020'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '0'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6) Tenaizus Woods (b) (4)	19 Apr 2021 14:52:49 05 Apr 2021 17:57:18
Signature has been broken.	Tenaizus Woods (b) (4)	05 Apr 2021 17:57:12
User entered 'No (N)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	05 Apr 2021 17:57:12
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 14:11:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
Signature has been broken.	Tenaizus Woods (b) (4)	05 Apr 2021 17:57:12
User entered '20 Feb 2021' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	05 Apr 2021 17:57:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered empty.	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'No (N)'	Bethany Evans (b) (4)	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User entered empty.	System	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User entered empty.	System	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:20
User entered empty.	System	28 Dec 2020 23:07:29

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
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)	16 Mar 2021 14:08:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 14:08:00
Data point term sent to Coder	System	16 Mar 2021 13:18:27
User entered 'Zofran'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'No (N)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'small bowel obstruction'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'UNK'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'UNK'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'other (OTHER)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'UNK'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered empty.	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered '31 Jan 2021'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered '0'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'No (N)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered '02 Feb 2021'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:51:26
User entered 'No (N)'	Monica Feeley (b) (4)	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User entered empty.	System	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User entered empty.	System	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:24
User entered empty.	System	16 Mar 2021 13:18:02

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, PRODUCT: ANALGESICS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:14:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:14:47
Data point term sent to Coder	System	24 Mar 2021 19:05:08
User entered 'pain medication (unknown)'	Monica Feeley (b) (4) (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'Small bowel obstruction'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'UNK'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'mg (mg)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered empty.	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'other (OTHER)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'UNK'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered empty.	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered '31 Jan 2021'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered '0'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered '02 Feb 2021'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:51
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User entered empty.	System	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User entered empty.	System	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:33:34
User entered empty.	System	24 Mar 2021 19:04:17

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:33:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:00
User closed query 'Add mammogram (20Feb21) to concomitant procedures' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 01:57:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 01:57:27
Query 'Add mammogram (20Feb21) to concomitant procedures' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:56:55
User opened query 'Add mammogram (20Feb21) to concomitant procedures' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:46:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 23:51:16

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Dec 2020 23:34:55
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 23:34:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Dec 2020 13:36:46
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 13:36:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 13:36:46
User entered '31 Dec 2020' (non-conformant).	(b) (4), (b) (6)	29 Dec 2020 13:36:46
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 23:52:50
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	28 Dec 2020 23:52:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 23:52:50
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	28 Dec 2020 23:52:13
User entered '31 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 23:52:13

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 13:36:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 13:36:46
User entered 'Left distal radius surgery - putting plate in' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 13:36:46
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 23:52:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 23:52:50
User entered 'Left Distal Radius surgery - putting in plate'	(b) (4), (b) (6)	28 Dec 2020 23:52:13

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#5 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:50:06
Query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#5 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'added concomitant procedure to AE' (Site from DM).	Austin Kim (b) (4) (b) (4)	05 Mar 2021 16:12:58
User opened query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#5 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:23:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 13:36:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 13:36:46
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 13:36:46
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 23:52:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 23:52:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	28 Dec 2020 23:52:13

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 01:29:49
User entered empty.	(b) (4), (b) (6) [REDACTED]	28 Dec 2020 23:52:13

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:42
User entered '01 Feb 2021'	Monica Feeley (b) (4)	10 Mar 2021 19:53:43

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:42
User entered 'X-Ray small bowel'	Monica Feeley (b) (4)	10 Mar 2021 19:53:43

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:42
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	10 Mar 2021 19:53:43

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:06:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:42
User entered empty.	Monica Feeley (b) (4)	10 Mar 2021 19:53:43

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:00
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:43
User entered '31 Jan 2021'	Monica Feeley (b) (4)	10 Mar 2021 19:53:58

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:00
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:43
User entered 'X ray chest'	Monica Feeley (b) (4)	10 Mar 2021 19:53:58

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:00
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:43
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	10 Mar 2021 19:53:58

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:00
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:47:43
User entered empty.	Monica Feeley (b) (4)	10 Mar 2021 19:53:58

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:45:11
User entered '31 Jan 2021'	Monica Feeley (b) (4)	10 Mar 2021 19:54:17

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:15:51
User closed query 'please correct spelling of CONTRACT to CONTRAST' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:15:49
Query 'please correct spelling of CONTRACT to CONTRAST' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Mar 2021 20:32:37
User entered 'CT WITH CONTRAST OF ABDOMEN AND PELVIS' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Mar 2021 20:32:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 17:49:48
User opened query 'please correct spelling of CONTRACT to CONTRAST' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:49:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:45:11
User entered 'CT with contract of abdomen and pelvis'	Monica Feeley (b) (4)	10 Mar 2021 19:54:17

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:45:11
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	10 Mar 2021 19:54:17

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:03
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:45:11
User entered empty.	Monica Feeley (b) (4)	10 Mar 2021 19:54:17

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 01:58:11
User entered '20 Feb 2021'	Monica Feeley (b) (4)	16 Mar 2021 20:32:04

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 01:58:13
User entered 'Mammogram'	Monica Feeley (b) (4)	16 Mar 2021 20:32:04

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 01:58:18
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	16 Mar 2021 20:32:04

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 01:58:20
User entered 'General Health'	Monica Feeley (b) (4)	16 Mar 2021 20:32:04

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:33:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered '09 Apr 2021'	Austin Kim (b) (4)	16 Apr 2021 20:23:47

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:33:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'breast biopsy'	Austin Kim (b) (4)	16 Apr 2021 20:23:47

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:33:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered 'Diagnostic (DIAGNOSTIC)'	Austin Kim (b) (4)	16 Apr 2021 20:23:47

US3432120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:33:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:07:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:02:02
User entered empty.	Austin Kim (b) (4)	16 Apr 2021 20:23:47

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '04/Feb/2021 07:23'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:33:05

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User entered '08/Mar/2021 09:44'	System	08 Mar 2021 15:44:36

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:33:05

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.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 16:52:02
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 15:44:36

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User entered '11/Mar/2021 11:52'	System	11 Mar 2021 16:52:18

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:33:05

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.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:17:35
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 16:52:18

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '17/Mar/2021 06:36'	System	17 Mar 2021 13:36:31

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:33:05

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:17:35
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 13:36:31

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '25/Mar/2021 06:18'	System	25 Mar 2021 13:18:23

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:33:05

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:17:35
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:18:23

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'USA-US078-2021-MRNA-1273-P301000012'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Yes (Y)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'No (N)'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Lindsey'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'Baden'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:23:11
User entered 'MA'	System	04 Feb 2021 12:21:10

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:43:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:44:19
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered 'US'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 13:17:26
User entered '5'	System	25 Mar 2021 13:18:23
User entered '4'	System	17 Mar 2021 13:36:31
User entered '3'	System	11 Mar 2021 16:52:18
User entered '2'	System	08 Mar 2021 15:44:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:29:49
User entered '1'	System	04 Feb 2021 12:23:17

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:33:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
User entered '30/Mar/2021 09:17'	System	30 Mar 2021 13:17:26

US3432120

Folder: SAE USA-US078-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:33:05

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:43:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:35:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:17:35
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 13:17:26